

# Creating a Sustainable Health Research Industry in Northern Ontario

October 2005



**Northern Ontario  
School of Medicine**

## Acknowledgements

For many years, Canadian physicians were primarily trained at medical schools situated in larger urban centres. Recognizing that the current medical training program could be better aligned with more regional needs, Northern Ontario communities came together with a unified vision to successfully establish a new Canadian medical school focused on addressing Northern health issues using innovative approaches to teaching, communication and clinical delivery. On September 2005, this vision was realized with the admission of the first medical class into the Northern Ontario School of Medicine (NOSM).

NOSM recognizes that the new medical school also represents a platform from which to develop an innovative health research community that addresses many of the needs and capabilities of Northern Ontario. To achieve this vision, the Health Research and Innovation (HR&I) Committee was formed representing many stakeholders in Northern Ontario health research. Recognizing the need to identify and create research strategies that are locally relevant, but globally competitive, the HR&I committee worked with SHI Consulting to create a report that not only identifies health research opportunities but also delivers the initial steps for implementation.

This report represents the culmination of SHI Consulting's research that spanned over twelve Northern Ontario site visits, in-person meetings with more than one hundred people, interviews with thirty leaders in government, academia, industry and non profit organizations, and benchmarking of five health research clusters that included thirteen interviews. This work could not have been possible without the generous support of numerous people, institutions and government agencies. In recognition of this support, NOSM would like to extend our sincere appreciation to all of those involved in this process.

The members of the HR&I Committee and SHI Consulting deserve special acknowledgement for their efforts in the developing and delivering of this report. We also wish to express our profound appreciation to the Northern Ontario Heritage Fund Corporation (NOHFC), FedNor, the National Research Council (NRC), the Federation of Northern Ontario Municipalities (FONOM), the Northwestern Ontario Municipalities Association (NOMA), the City of Greater Sudbury, the City of Thunder Bay, the City of Sault Ste Marie, the City of Timmins and the City of North Bay for their participation and generous financial and in kind support necessary for the completion of this process.

This report represents many of the possible avenues to create a new and innovative health research economy in Northern Ontario. We are confident that with the passion, energy and support that was clearly demonstrated during this process, a strong and vibrant health research community will develop in Northern Ontario.



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## **Executive Summary**

This summary gives a brief overview of each of the strategies put forward to grow the health research industry of Northern Ontario. The first part of the document focuses on the outputs of the economic modeling undertaken as part of this work. This is presented graphically. It considers the background economic scenario of Northern Ontario, then what effect the establishment of the Northern Ontario School of Medicine (NOSM) may have on this scenario. The next part of the modeling shows the effects of implementing the strategies and initiatives put forward in this document.

A description of the overall strategy follows the economic modeling. This includes a brief review of clusters and their benefits and limitations followed by a description of a new cluster paradigm termed “hubs and nodes”. The strategy put forth in this document aims to bring together the dispersed research assets and activities in Northern Ontario to create a research node that can link with other sites within the provincial, national and global community.

### **Northern Ontario/Canadian Hospital Research**

The Canada Foundation for Innovation (“CFI”) will issue requests for proposals for several major funding initiatives, one of which will be done jointly with the CIHR, which can potentially assist the Northern Ontario region in satisfying its health care delivery, research, and economic objectives.

These initiatives are particularly relevant to NOSM, for its regional (or pan-Canadian) health care delivery and research strategy, and to individual research hospitals that desire to put their own funding mechanisms and strategic plans into place.

In order to capitalize on these potential (and time-sensitive) opportunities, a strategy is required to link new and existing strengths in the region, enhance globally competitive assets and leverage these opportunities for regional, and potentially pan-Canadian, development and economic growth. While it is recommended that NOSM play an important role in this initiative, the Hospital community must also play a critical role.

The amount of funding projected to be available to Northern Ontario associated with the current round of CFI applications is likely to be in the range \$20-50M, including funds from all appropriate CFI and CIHR initiatives and matching funds from various provincial and private sources.

Clinical health care delivery and health research activities in Northern Ontario are removed geographically from those occurring in major urban centres. For this reason, it has been difficult to recruit highly qualified medical, research, and technical support staff to Northern Ontario, including those in the industrial and capital sourcing industry, which in turn impacts significantly on the economic well-being of the region. In addition, the dispersed nature of health care delivery resources in Northern Ontario also results in reduced access to medical care for many people in the region, particularly more remote populations.

Together, these issues constitute historical barriers to the development of effective and efficient health care practices and health sciences research in

the Northern Ontario region. The Northern Ontario region is thus in a similar position to many other Canadian jurisdictions which, with the exception of major urban centres, also have dispersed nodes of expertise and populaces spread out across large distances.

NOSM presents a unique opportunity for Northern Ontario to “reset the clock” on many of its historical barriers to the development of leading edge health care practices, and for the new medical school to take a strong leadership role in health care delivery and research Northern Ontario.

In September 2005, the new Northern Ontario School of Medicine will begin offering classes for 56 medical students. NOSM is the first medical school in Canada to be built in more than 30 years and represents a unique opportunity for training and locating of clinicians and researchers in a rural setting. This program has recruited numerous faculty members and local clinicians, and the intent is to further attract and retain highly qualified clinical, research and technical support personnel.

The inception of NOSM brings new leadership and assets into the regional health science spectrum. This provides Northern Ontario with a significant and unique opportunity to leverage these assets and create synergies among regional clinical, research and health care delivery resources, including industrial and capital source partners, in order to better serve its rural population base and bring a new level of economic vitality to the region.

The inauguration of NOSM therefore presents a unique opportunity for Northern Ontario not only to “reset the clock” on many of its historical barriers to the development of leading edge health care practices and health sciences research in the region, but also to take a strong leadership position in developing a national research network of northern/rural hospitals and medical centres with similar challenges and objectives.

### **Community-based Health Research Network**

This initiative focuses on community-based clinical health research, which will be highly inclusive of centres in Northern Ontario and will give an opportunity for practising clinicians such as physicians, nurses, therapists and pharmacists to participate in research.

A clinical health research network of this type is particularly relevant to the grid strategy as it would have a central core with several other points of presence in the main centres in Northern Ontario. Its scope and reach would be across the region and would specialize in conducting and teaching methodology for clinical research across multiple, geographically dispersed centres of clinical care. There would be a strong focus on research into clinical outcomes to modify delivery management approaches to achieve improvements in this. Some work of this nature has already been undertaken in Northern Ontario and this will build considerably on that.

This will answer clinical questions relevant to Northern Ontario, while positioning the region well to participate in clinical research. There is a strong shift in funding towards this type of research in Canada.

The concept would link NOSM with all the main centres across Northern Ontario. Its clinical hub should be located outside of Sudbury or Thunder Bay in order to facilitate partnership and collaboration between all participating consortium members.

As a result of social, economic and geographic circumstances aboriginal peoples often have unique healthcare needs also reflective in their healthcare needs.

Additional infrastructure will be needed for these research centres. There are a number of sources of possible funding for this, including the CFI New Initiatives fund and the cities where it would be located.

### **First Nations Health Network Concept**

As a result of social, economic and geographic circumstances, aboriginal peoples often have unique healthcare needs. These needs are served both within aboriginal and non-aboriginal healthcare environments. Often cultural complexities, differences and history have prevented these groups from working together to exchange ideas and capabilities that would be beneficial to both communities. To bridge this gap, an area of common ground (e.g. a shared resource) would enable stakeholders to come together and exchange ideas. This shared resource could be used as a learning centre, to work on shared research projects, as well as a knowledge exchange centre. The maintenance and governance of such an initiative would be jointly shared by stakeholders. This centre of common ground is envisioned as a potential gateway between communities where resources can be shared and projects developed.

### **Ethics Review Boards – Agreed Standards & Mutual Recognition**

Ethics review boards perform an extremely important function by ensuring that clinical research that is carried out meets appropriate ethical standards. When conducting clinical research, accessing sufficient numbers of patients often requires research to take place at multiple centres and hospitals. This results in a lot of duplicated process, with the same project having to pass through multiple review boards.

The objective of this initiative is to have agreed standards across the region that would pave the way for mutual recognition of decisions while still allowing particular sites to do a local verification of ethics approval. This will allow multiple sites to give approval to a project through a single application process, and will create a competitive advantage for the region, making it more attractive to do research there.

This is a key enabler of the collaborative and multi-centre nature of the proposed disbursed, networked research grid.

### **Proteomics and Genomics Grid**

An internationally competitive genomics program could be created by harnessing the unique assets of Northern Ontario's research network and geo-demographic base. Specifically, a unique genomics centre could be created by bringing together both nuclear and mitochondrial DNA research. By working through organizations such as the Public Populations Project in Genomics (P3G), this centre would focus on standardization within the genomics arena and should enable Northern Ontario to engage in globally competitive research.

A diverse set of regional assets can contribute to building a viable and strong genomics grid. For example, genomics researchers, doctors and local community members could all participate by examining, collecting and donating tissue samples respectively. Even with a limited amount of funds, the genomics initiative can enter the global arena within one year by joining P3G. Once this international validation occurs, a wide variety of potential

Ethics Review Board harmonization is a key enabler of the collaborative and multi-centre nature of the proposed disbursed, networked research grid.

funding sources would be more supportive in such an initiative and many different projects could be supported.

### **Bio-prospecting**

Bio-prospecting for pharmaceutical compounds is the search for economically valuable biological molecules, organisms, or genetic material from nature. Northern Ontario is a vast and diversified region rich with natural resources, which makes the region an excellent location for conducting bio-prospecting. In addition to aboriginal knowledge in natural medicine, the region is host to several academic research groups and networks that have developed expertise, technologies, and databases that could be leveraged in a bio-prospecting initiative.

The recent decrease in productivity in pharmaceutical discovery has promoted the search for new ways to discover drug leads. The bio-prospecting initiative aims at making Northern Ontario an internationally recognized centre for bio-prospecting. The consortium will provide leadership to bring multiple stakeholders into a multidisciplinary endeavor that will leverage one of the largest national 'libraries' of bio-products e.g. the Canadian North.

Key infrastructure and equipment will include GPS based systems, web-enabled data management systems, analytical laboratories, molecular and cellular biology laboratories, as well as teaching facilities. Communication will be channeled through a project manager that will coordinate the activities and communicate progress to the member with the aid of communication infrastructure such as video-conferencing. The bio-prospecting initiative will seek funding from federal agencies such as the NCE, CRC, and CFI as well as from local partners such as FedNor and NOHFC. Drug discovery is a risky endeavor, and multi-national pharmaceutical companies now recognize that diversification will be critical to scientific success as well as strategic partnerships with non-traditional partners.

### **Collaborative Interdisciplinary Research and Commercialization Fund**

Innovation occurs when interdisciplinary research intersects with highly qualified graduate students and research personnel. Northern Ontario has historically lacked some of the enablers to promote these strong collaborations, and now desires to aid in promoting academic excellence. To achieve this, a specific research fund could be created that would promote collaborations and attract highly qualified graduate students, post-doctoral fellows and researchers while creating innovative training regimes to further serve to promote interactions. Though a multi phased process, this fund would also enable the development research projects past the proof of concept stages and towards early commercial potential. Therefore internationally competitive science would be promoted while commercial opportunities would be identified and brought forward over a 5-10 year time horizon.

### **Research Chairs and Fellowships**

The initiatives proposed in the current strategy for developing the health sector will require leaders and highly qualified personnel. These resources are comparatively sparse in Northern Ontario and therefore significant initiatives are warranted to attract, retain and support current and future local leaders.

Chairs, fellowships and a rigorous research environment are critical to developing the health sciences sector in Northern Ontario.

Further support is also warranted to attract and retain professional staff and students.

Research chairs and fellowships are an important aspect of the human resource strategy proposed in this document. In particular, the strategy proposes the creation of high profile positions for leaders in the strategic fields of bio-prospecting and genomics/proteomics. It further proposes a program that will support students through fellowship and fellowship supplements. Its vision is to make the region a rewarding environment to pursue a career in medical research. By creating chairs and fellowships, it will provide strong incentives to retain and attract true leaders to champion Northern Ontario featured projects. Faculty representatives will oversee that chairs and fellowship are available to attract, retain, and foster local champions for its initiatives. In order to attract true leaders, the programs should be aligned with research support and a dynamic environment to conduct science.

### **Regionally Focused Venture Seed Fund**

For a regional biotechnology sector to prosper, access to risk capital and industrial funding is critical.

The current Northern Ontario economic strategy has put an important emphasis on the development of the health and biotechnology sector in the region (e.g. NOBI). The health research and biotechnology industry have fairly unique business models where risks are generally high and timelines for returns generally long. For such an industry to develop and prosper, access to 'risk money' is crucial. It is thus very important that such funding capabilities be developed in the Northern Ontario region to foster the potential economic outcomes of the current initiatives and to develop the health industry. The aim of the proposed fund is to provide seed funds to Northern Ontario biomedical entrepreneurs that have promising ventures with potential for high economic returns. Northern Ontario entrepreneurs currently have very little access to funds for risky endeavors such as those in the biomedical and biotechnology sector. With capital of \$2.5M, the fund will provide seed financing of \$50-250K, with an investment horizon of 5 years. In coordination with an advisory board a fund manager will evaluate funding opportunities and secure potential follow on investments from key VC partners. To mitigate the increased financial risk due to the challenging environment, the fund will comprise 50% public equity and the fund manager will develop close relationships with local stakeholders and with VCs in Toronto. Success factors depend on the ability to build an entrepreneurial culture that is biotech savvy, to stimulate a critical mass of opportunities, and to foster a pool of human resource for the developing industry.

### **Direct Investment into Academic Labs by Private Bioscience Companies**

Besides educational purposes, research activities serve as an engine for innovation and long-term economic development. The latest advances in biomedical research have raised the field to a point where research outcomes can have immediate or short-term impacts on medical practices and drug discovery. This is why industry and academic research have grown closer together in the last decade. Northern Ontario's current and emerging assets in medical research thus provide the region with many commercial opportunities which should be leveraged to attract private funding in the on-going research activities. Researchers in Northern Ontario are developing tools and making discoveries that may have value to the right private partner; the direct investment committee will provide local leadership in industry

relationships and global awareness of the region's value proposition. The direct investment strategy would be directed by a committee of experienced stakeholders that will bring together their experience and resources. The operations of this committee should be led by the united Technology Transfer Office partners. The direct investment initiative should require around \$100K for start up and assemble an operating budget of \$50K for initiatives and promotional activities.

### **Network of Technology Transfer Offices**

Provided that the additional investments proposed for biomedical research are available in Northern Ontario, an increasing number of commercial opportunities are likely to arise. To best seize these opportunities, effective technology transfer processes should be in place and resources made available. Such a function requires access to a range of professionals, such as corporate lawyers, intellectual property specialists, and business development professionals. The task of technology transfer is a daunting one that requires skills that warrant a multi-disciplinary team.

However, such a team of highly qualified professionals needs to be leveraged through a large enough portfolio of technological opportunities. Given the limited volume of technology in the several Northern Ontario institutions, there is not a critical mass that justifies creating such a team in every institution. The context thus warrants creation of a network of technology transfer professionals that would share resources to oversee the larger portfolio of Northern Ontario technological innovations. This initiative thus aims at bringing together regional resources in technology transfer to leverage highly qualified personnel through the larger portfolio. It is imperative that resources and processes be effectively deployed in the region to empower investigators and entrepreneurs to actualize their commercial opportunities.

### **Research Park and Incubator Network**

Normally, biomedical research spin-offs arise from a promising technology that needs further development prior to generating revenue. This is a critical period where firms need access to a wealth of resources, but are in a high risk position and have very limited funds. This is why most, if not all, biotechnology clusters were developed to provide incubator facilities that offer both rental spaces and professional services to leadership of young ventures in order to help them develop their technologies to the point where they can generate revenue or attract sufficient investment to build their own facilities. The incubator initiative proposes a complete repertoire of services and infrastructure to accompany emerging biomedical companies toward corporate success. There will undoubtedly be a growing need for physical space and professional services as commercial ventures spin-off from research activities in the region and facilities should be available to host entrepreneurs. The Biomedical Research Venture Incubator should be a non-profit organization with a Board of Directors comprising of key regional stakeholders. The virtual incubator organization would manage a flexible portfolio of real-estate spread across the region, and provide IT infrastructures and links to professional services. The success of the virtual incubator will depend on the success of the development of the biomedical industry in Northern Ontario and the ability of the incubator management to efficiently forecast the needs and manage its portfolio of real-estate efficiently.

To facilitate success of emerging biotechnology companies, a repertoire of strong leadership, services and infrastructure will be necessary.

### **Liberal, Harmonized Intellectual Property Policies**

To achieve success in commercialization of health research in the region, the varying intellectual property policies of the different institutions across the region will need to be harmonized. Most important of all, they will need to be liberal in the rights accorded to investigators to profit from their discoveries.

This initiative focuses on aligning intellectual property policies across the region so that they are consistently liberal and harmonized in nature. Such policies already exist at universities in Northern Ontario, but should extend to hospitals and other clinical centres where original research will be conducted over the coming years. Despite the current legislative environment for hospitals, this can be done with the right legal structures.

Such policies are a competitive edge in attracting and retaining top researchers from larger centres, because these people would be able to profit from the commercial applications of their discoveries.

## **Glossary of Acronyms**

CFI	Canada Foundation for Innovation
CHRP	Collaborative Health Research Projects
CHSRF	Canadian Health Services Research Foundation
CIHR	Canadian Institutes for Health Research
CRaNHR	Centre for Rural and Northern Health Research
CRC	Canada Research Chair
CVD	Cardio-Vascular Disease
EDC	Economic Development Corporation
EU	European Union
FDA	Food and Drug Administration
GHC	Group Health Centre
GIS	Geographic Information System
GPS	Global Positioning System
HPID	Health Promotion Initiative for Diabetes
HQP	Highly Qualified Personnel
ICR	Institute of Cancer Research
IMO	Innovation Management Office
IP	Intellectual Property
IPM	Intellectual Property Mobilization
IPMO	Intellectual Property Management Office
IPO	Initial Public Offering
LOI	Letter of Intent
LSSU	Lake Superior State University
MaRS	Medical and Related Sciences
mtDNA	Mitochondrial Deoxyribonucleic Acid
NCE	Networked Centres of Excellence

NEORCC	North Eastern Ontario Regional Cancer Centre
NEUREKA!	Northern Centre for Biotechnology and Clinical Research
NOBI	Northern Ontario Biotechnology Initiative
NOHFC	Northern Ontario Heritage Fund Corporation
NOSM	Northern Ontario School of Medicine
NGO	Non-Governmental Organization
NSERC	Natural Sciences and Engineering Research Council
NWOCRI	North Western Ontario Cancer Research Institute
ORF	Ontario Research Fund
ORION	Ontario Research and Innovation Optical Network
P3G	Public Population Project in Genomics
PGx	Pharmacogenomics
RIN	Regional Innovation Network
SSHRC	Social Sciences and Humanities Research Council of Canada
SWOT	Strengths, Weaknesses, Opportunities, Threats
UBC	University of British Columbia
ULERN	Upper Lakes Environmental Research Network
WSIB	Workplace Safety and Insurance Board
VC	Venture Capital
VIP	Vascular Intervention Project

## **Introduction**

### **I. Rationale for the Project**

Despite the range of existing resources, there have been significant historical barriers to the development of leading edge health care practices and health sciences research in the Northern Ontario region.

The new Northern Ontario School of Medicine (NOSM) will be opening its doors in the fall of 2005. Fifty-six students will begin their medical training in a program that is tailored to the health care needs of the Northern Ontario region. The program already encompasses numerous faculty members and local clinicians and fully intends to attract and retain highly qualified personnel in numerous areas, including health care delivery, health science research and associated support systems e.g., nursing, administration, medical testing and analysis, technology transfer, venture capital, management, information and telecommunications specialists etc.

While NOSM is a recent medical initiative, the Northern Ontario region already hosts several health research programs in basic and clinical research, including those in population health/public health issues, diseases/disorders specifically affecting northern populations, occupational health, evaluation of health and health education delivery approaches and healthy aging.

Despite the range of existing resources, there have been significant historical barriers to the development of leading edge health care practices and health sciences research in the Northern Ontario region. Primary among these is the dispersed nature of health care delivery resources in Northern Ontario, which has resulted in reduced access to medical care for many people in the region, particularly for more remote populations. Distance from major urban medical centres has also made it difficult to attract highly qualified personnel to the region, and this has resulted in the lack of a critical mass of expertise in the region. In addition, opportunities to partner and collaborate with clinicians, researchers and other health care specialists, including industrial and capital source partners, have been minimized due to the lack of geographic proximity between these resources and those in Northern Ontario.

The inauguration of NOSM in September 2005, presents a unique opportunity for the Northern Ontario region to “reset the clock” on many of these historical barriers.

However, the inauguration of NOSM in September 2005, presents a unique opportunity for the Northern Ontario region to “reset the clock” on many of these historical barriers. In particular, the increased capital, infrastructural and human resources associated with NOSM each represent substantial leverage points for developing a critical mass of clinicians, researchers and support personnel. For example, recent investment in information and telecommunications technology and infrastructure has substantially minimized functional distances between resource nodes within Northern Ontario and other locations within Canada and globally. Importantly, this is expected to open up new doors for partnership and collaborative activities not only relating to health care delivery and research, but also those relating to commercialization of technology and regional economic development.

NOSM brings with it new and expanded leadership assets to the regional health science spectrum, which in turn provides Northern Ontario with a significant opportunity to create synergies among regional clinical, research and health care delivery resources. This will allow NOSM, and associated

health care resources, to better serve the rural Northern Ontario population base and bring a new level of economic vitality to the region.

In order to capitalize on these potential opportunities, a strategy is required to link new and existing strengths in the region, enhance globally competitive assets, and leverage opportunities for regional development and economic growth.

As northern and rural health research and innovation is emerging quickly as a “hot button” issue, success in growing a specialized health research program in Northern Ontario would provide economic development and diversification benefits. In addition, navigating through the demands and risks associated with taking a unique discovery or invention to highly regulated global markets is challenging, yet the rewards can be very substantial. As a result, it is essential to find appropriate niche areas in which NOSM can specialize and partner, and where excellence and competitiveness can be sustained and investment risks minimized.

Finally, the positive effects of resource convergence due, in part, to expanded information and telecommunications technologies, has not gone un-noticed in Canada, particularly as it relates to new federal funding opportunities and initiatives. In order to capitalize on these potential (and time-sensitive) opportunities, a strategy is required to link new and existing strengths in the region, enhance globally competitive assets, and leverage these opportunities for regional development and economic growth. Therefore, an effective strategy is needed with a practical implementation plan to accelerate the growth of the health research sector in Northern Ontario over the next decade.

## II. Economic Situation in Northern Ontario

Key information from the economic modelling that was undertaken with this work is provided in this section. It shows the economic situation in the region without the effect of establishing the medical school as a Base Case. It then shows what the effects are of establishing the school and finally, the effects on economic growth of the Grid Scenario of networked research that the initiatives in this report are designed to create. Further detail of the economic modelling, including technical methodology and other scenarios are included as an appendix to this report.

### **Base Case**

The population possibilities for Northern Ontario are computed and subdivided into risk and reward regions. The demarcation between risk and reward regions is established by the maximum density of the simulation results, and the motivation of the region. The maximum density could be interpreted as the central tendency of all the population possibilities as weighted by probability. This type of central tendency is referred to as a “gauge expectation” as it is used as a measure of whether a possible scenario comprises a risk or reward given a particular motivation.

The motivation of the region is assumed to be the maximization of the population base. As a result, a drop in the population (red) below the gauge expectation (blue) is considered a risk to the Northern Ontario economic perspective, and an increase in the population (green) above the gauge expectation (blue) is considered a reward to the Northern Ontario economic perspective. The results of simulation are as follows:

The results show a decline in the population of Northern Ontario over the simulation period.

**Figure 1. Northern Ontario Population Simulation with Upper & Lower 95% Confidence Intervals**

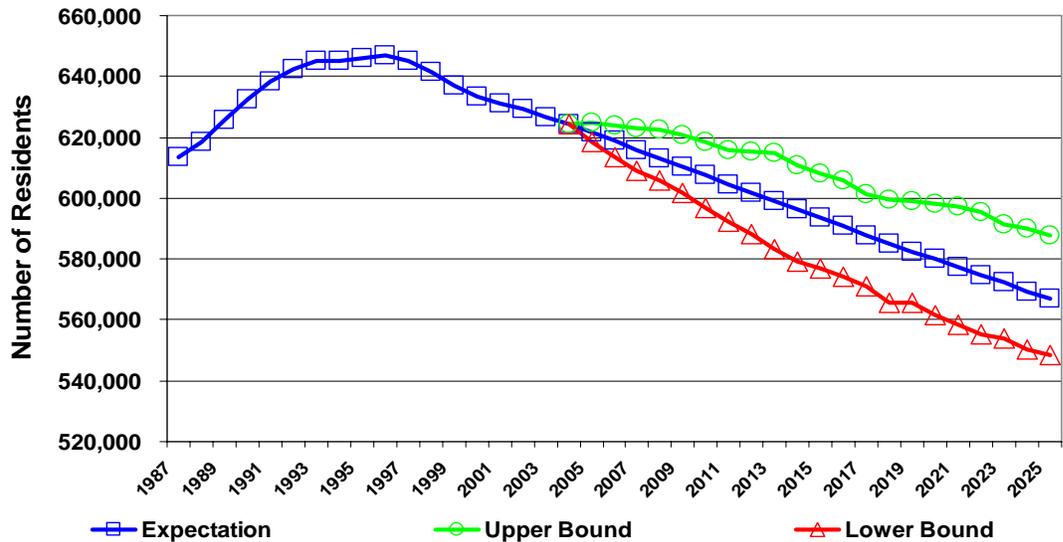
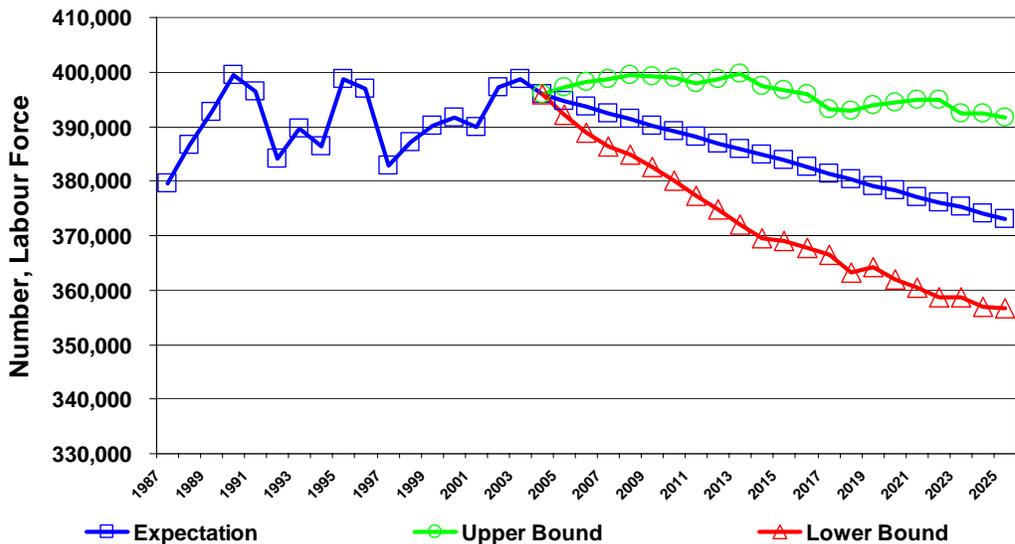


Figure 1 shows a decline in the population of Northern Ontario over the simulation period, being from 2004 to 2025.

Labour force simulations are conducted in the same way, with the results being:

**Figure 2. Northern Ontario Labour Force Simulation with Upper & Lower 95% Confidence Intervals**

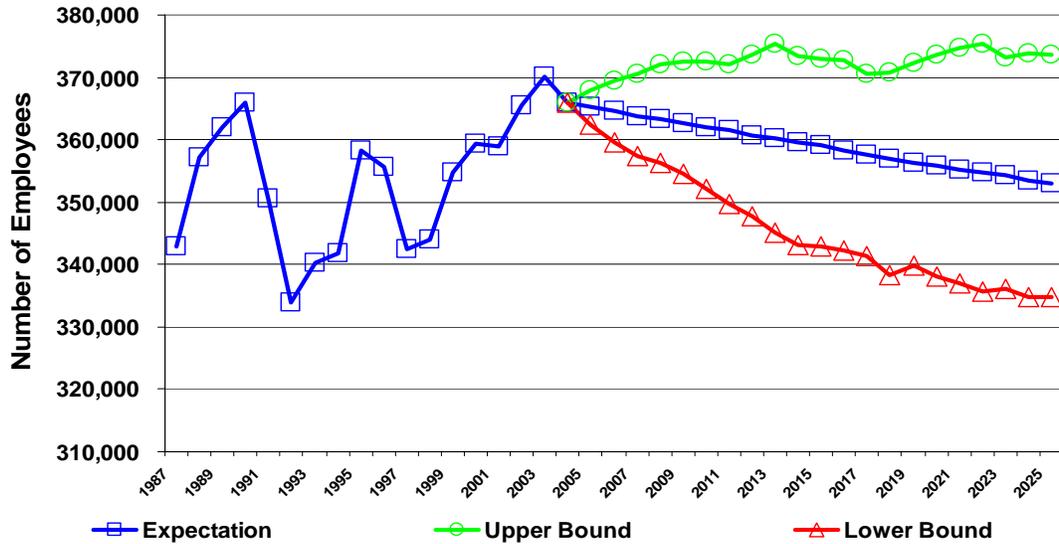


The labour force results show a resilience of the Northern Ontario economy to change with the declining population structure. This is indicative of a population base that is increasing its participation rate to enter the work force.

The data show a relative resilience to change in labour force and employment.

Employment simulations are conducted in the same way, with the results being:

**Figure 3. Northern Ontario Employment Simulation with Upper & Lower 95% Confidence Intervals**



Again the employment results show a resilience of the Northern Ontario economy to change with the declining population and labour force structure. This is indicative of a labour force that is prepared to change its skill base, improve efficiencies and to take up unemployment slack.

A key issue that emerges however, is that despite the resilience of the labour force and the employment base to resist a falling population profile, the ability to resist is not unlimited. In this way, a future path that tracks into the risk regions (red) as indicated will accelerate the reduced ability of the region to manage economic decline. A future path that tracks into the reward regions as indicated (green) will decelerate the reduced ability of the region to manage economic decline and potentially change the momentum in favour of regional economic managers to build a new foundation upon which economic resources are attracted to the region.

**Effect of Establishing the Medical School**

While the medical school is a pre-existing project, its impact upon the statistical history is not yet realized. For this reason, the medical school is treated as a scenario that is incremental to the base case.

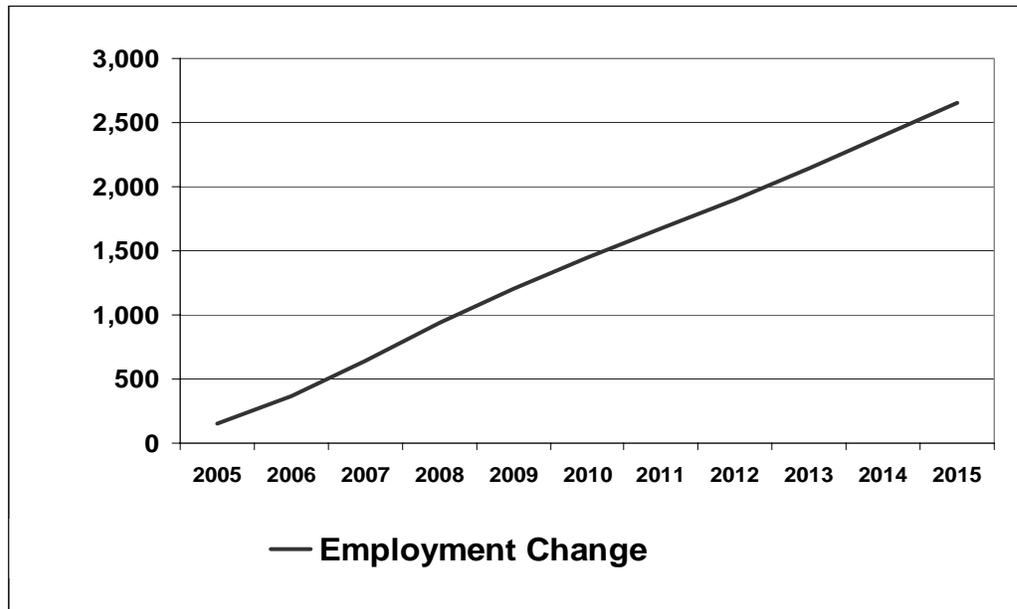
**Figure 4. Total Employment Trend Resulting from Addition of NOSM**

Figure 4 shows the total employment trend resulting from the addition of NOSM to Northern Ontario.

The employment results are robust indicating a strong platform from which other initiatives can be based.

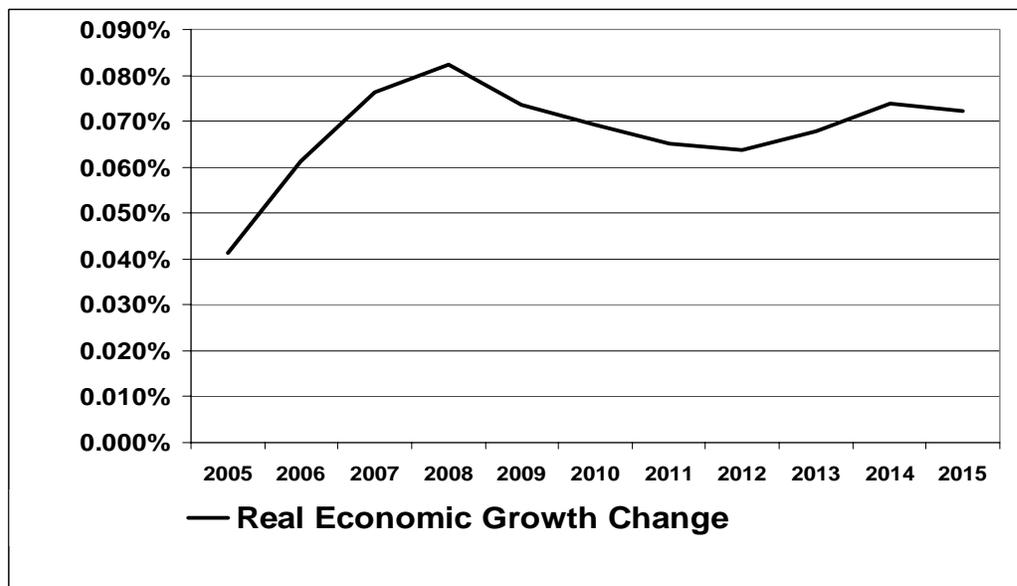
**Figure 5. Change in Real GDP for Northern Ontario**

Figure 5 shows the change in real GDP for Northern Ontario each year, and does not include a compounding for pervious years. That is a change in a particular year is in addition to the changes in previous years.

The financial performance is cyclical as indicated by these two charts. While the net present value results of this scenario is expected at \$4.4 million for the Northern Ontario economy as a whole, the positive results do not occur until 2013. This reflects the slow-moving value-added nature with a risk period that extends from 2005 to 2012.

Figure 6 below shows the net rate of return for the Northern Ontario economy adjusted for time value for each year taking into account all previous years

**Figure 6. Net Rate of Return for Northern Ontario's Economy**

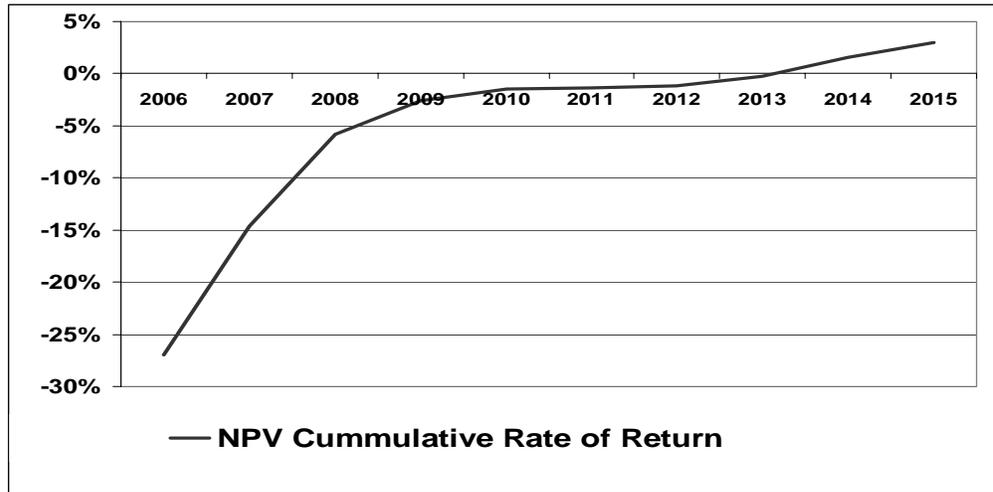
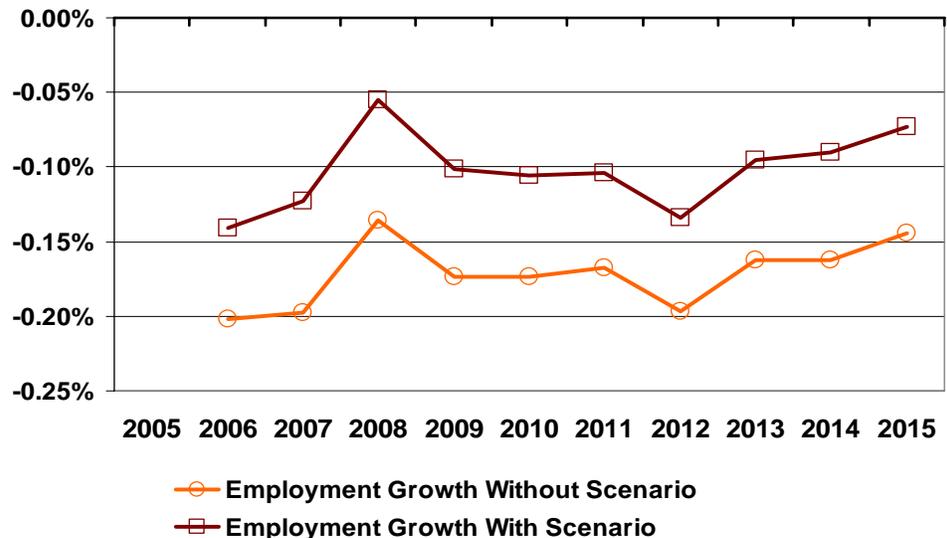


Figure 7 shows the base case projected employment growth and the employment growth that is expected to be exhibited with the success of NOSM. This chart shows how the scenario elevates the expected employment growth/decay rate proportionally throughout the simulation period.

**Figure 7. Projected Employment Growth With and Without Scenario**



### Health Research Grid

This scenario assumes the implementation of the medical school scenario and the results show the incremental results (in addition to) over and above the medical school results.

This scenario is a slow starter requiring the effects of compounding from subsequent spending and investment cycles to progressively larger impacts through time. While being a slow starter, the scenario shows significant potential for stable reward.

**Figure 8. Total Employment Trend with Implementation of Grid Strategy Initiatives**

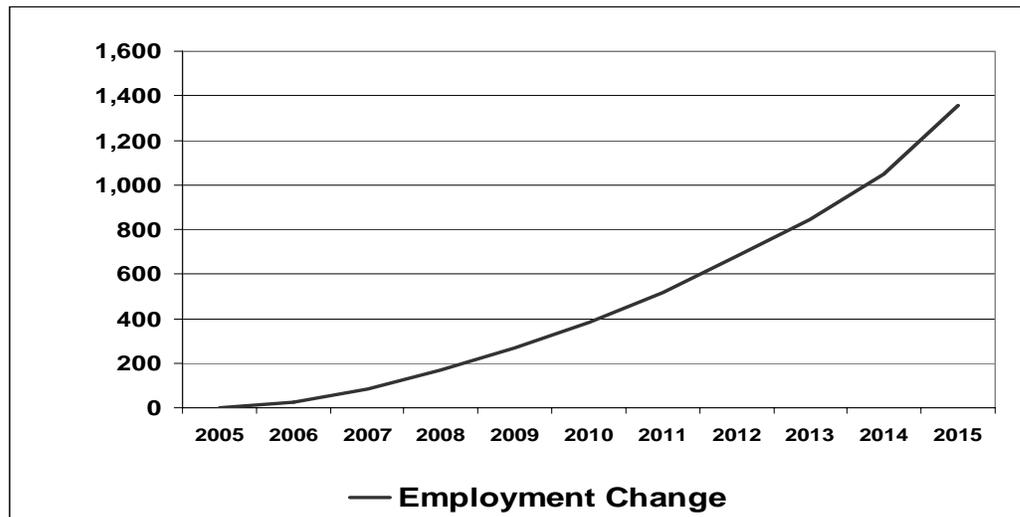


Figure 8 shows the total employment trend resulting from the implementation of the initiatives of the grid strategy. Notice how the scenario is non-linear and accelerates through the simulation period.

**Figure 9. Change in real GDP with Implementation of Grid Strategy Initiatives**

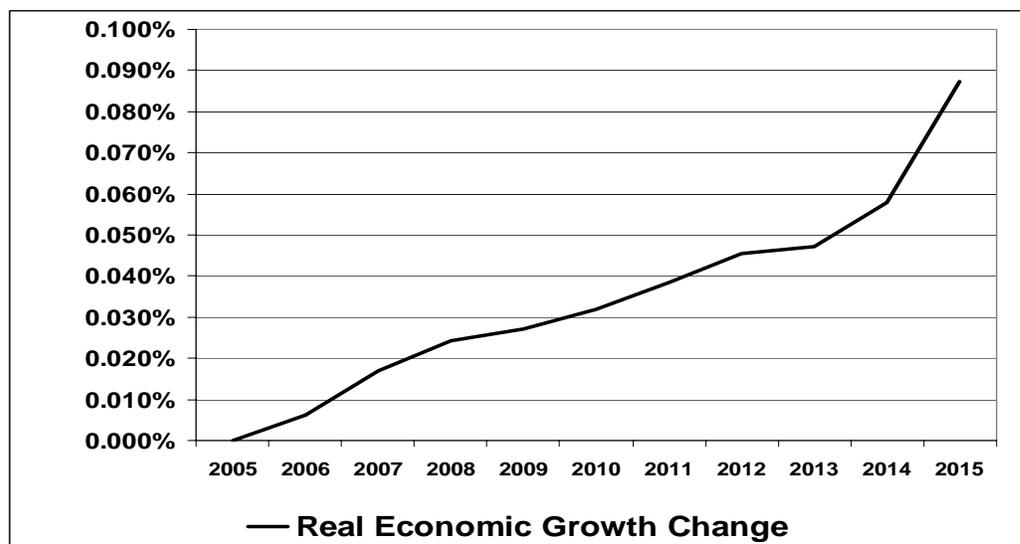


Figure 9 shows the change in real GDP for Northern Ontario each year, and does not include a compounding for previous years. That is, a change in a particular year is in addition to the changes in previous years. This chart shows how the scenario generates strong real GDP growth from 2009 onwards. While the net present value results of this scenario is expected at \$15.6 million for the Northern Ontario economy as a whole, the positive results do not occur until 2014. This reflects the risk associated with this scenario which, if managed appropriately, is expected to result in commensurate rewards.

**Figure 10. Net Rate of Return with Implementation of Grid Strategy Initiatives**

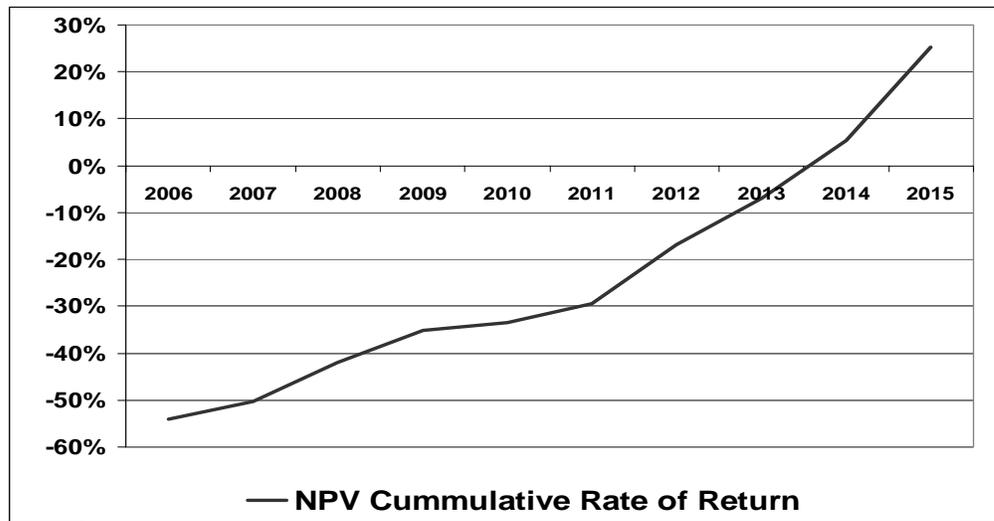


Figure 10 shows the net rate of return for the Northern Ontario economy adjusted for time value for each year taking into account all previous years. With the large reward potential from a relatively lower investment base, there is risk.

**Figure 11. Projected Employment Growth With and Without Scenario**

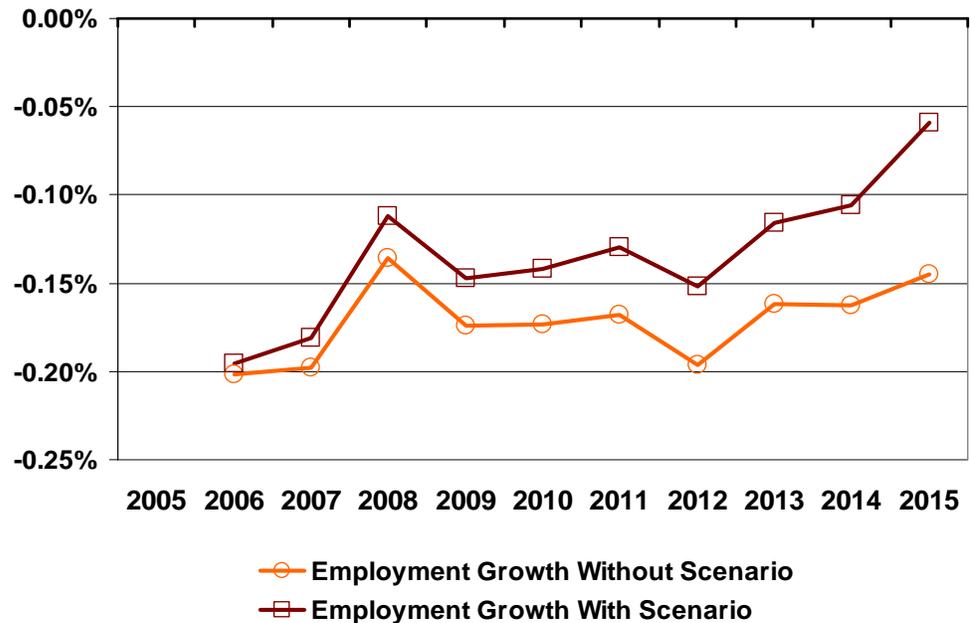


Figure 11 shows the base case projected employment growth and the employment growth that is expected to be exhibited with the success of the scenario. This scenario progressively adds employment potential to the economy as time passes.

The Research Grid scenario is a refinement of the Dispersed Networked Health Research scenario that was put forward mid-point in the project in the discussion document developed at that time. Economic analysis of the different strategic scenarios and the discussion document are included as appendices to this report.

### III. Three Scenarios to Build a Healthcare Cluster

#### The grid strategy

##### *Clusters, Hub and Nodes*

Clusters are concentrations of related products and services that are able to fulfill the needs with a value chain.

Creating therapies to improve health has always been a central tenet of the biotechnology industry. This “bench to bedside” process requires a diverse number of activities ranging from research and clinical testing to manufacturing and marketing. Traditionally this process was the domain of large pharmaceutical companies, but as the drug design and discovery process became more complex opportunities have arisen for firms to specialize in various processes. Innovation was also driven from academic centers of excellence. From these centres, technology was created, advanced and finally spun out. This led to the creation of resident biotechnology clusters in areas that did not traditionally have large pharmaceutical companies.

Clusters, as defined by Michael Porter, are concentrations of related products or services in a related industry<sup>1</sup>. This model has been applied to various industries ranging from entertainment to aerospace and medical device / biotechnology. By bringing together related personnel and services, groups such as government, academia, industry and NGOs are able to share similar support services, face similar challenges and seize opportunities in a cohesive manner. With the cluster responding together to market forces in unison, greater opportunities are realized as group members are able to act more efficiently than they would individually.

Clusters are now sub specializing into Hubs and Nodes and Northern Ontario is positioned to capitalize on this evolution.

Traditionally, communication and logistics have kept clusters together cohesively. With changing market dynamics, the traditional requirements of companies have changed to reflect a new paradigm. Rapid advances in shipping, communication and trade have created the opportunity for regions to subspecialize in one aspect of a traditional cluster. This is termed *Global Hubs and Nodes*<sup>2</sup>. Perhaps the most striking example is the computer industry. In the 1970s and 1980s, this industry’s research and design, manufacturing and distribution were all centralized in Silicon Valley. Today, components are designed in Silicon Valley, manufactured in China and either assembled in Taiwan or Texas (e.g. Dell Computer). With each region specializing in one particular aspect of the value chain, the relevance of geographic proximity can be replaced in part by subspecialization. For example, in the life sciences, Puerto Rico has become a well recognized node, since it is only known for drug manufacturing and not other services such as R&D. Thus global forces are competing through the hub and node model to link areas of excellence.

The creation of a node is the next stage in the evolution of competing global forces. To extrapolate from the history of cluster development, these nodes do not need to be physically situated in close proximity. Medicon Valley is a well-known benchmark, yet the life science’s cluster that spans Copenhagen

<sup>1</sup> Porter, ME. (1990) *The Competitive Advantage of Nations*. New York: The Free Press

<sup>2</sup> New Economy Strategies. (2005) *Global Hubs and Nodes: A white paper on new paradigms in regional development*.

in Denmark and Skåne in Sweden<sup>3</sup>, crosses international borders. In the EU, there are incentives and encouragement for cross boarder partnerships, whereas in North America, incentives to collaborate are only within a city, province or state<sup>4</sup>.

### ***Is Northern Ontario a node?***

NOSM will aid in linking the major health centres across Northern Ontario.

Northern Ontario is a region characterized by a dispersed collection of cities, towns and municipalities. Each brings with it its own collection of expertise and skills. The central problem of an area or region with dispersed resources is that critical mass has not developed that would allow for significant life science research and innovation. In 2005, this will begin to change with the completion of the Northern Ontario School of Medicine. This school is unusual in that the school is a corporation unto itself, owned equally by Laurentian University in Sudbury and Lakehead University in Thunder Bay. The board of directors of the corporation is community-based, reflective of the population of Northern Ontario. This infrastructure will also aid in linking the variety of research groups between cities.

Since these assets are relatively dispersed and are not all focused on one specific area, this is termed a resource “grid”. The grid enables research to attain critical mass and help drive the research agenda.

Dispersal is thus the major theme for Northern Ontario. This region contains six centres that are divided between the Northeast and Northwest areas of the province. In the life sciences and healthcare research realm these centres have operated independently with little communication which has prevented the region from achieving the critical mass required to rapidly innovate. However, NOSM presents an opportunity to shift the dynamics within the region. The unique aspect of this medical school is the equal division between the Northeast (Sudbury) and the Northwest (Thunder Bay). This school represents a major healthcare link between the two and their respective outlying areas. What has traditionally been a barrier for growth can now be turned into an advantage with the new school.

NOSM represents a major healthcare link between the two and their respective outlying areas.

The type of health, research and innovation network that can be created in Northern Ontario will, in part, be governed by geography as well as institutional assets. The geography of the region is against becoming a classical cluster as defined by Porter as these are more physically concentrated. Therefore, within the life science development value chain, it will be practical to concentrate on being good at particular parts of the value chain. The next question is whether this region can become a global hub or node. With the hub being a central aggregator of a collection of nodes, Northern Ontario will likely not be ready for this positioning. However this community can be positioned to become a node within the global research and development market by specializing in core areas and partnering internationally.

<sup>3</sup> Frank L. (2002) *Nature Biotechnology*. Biotechnology in the Medicon Valley. (20) 433-435.

<sup>4</sup> Friedman, YE. and Seline, RS. *Nature Biotechnology*. Cross-border biotech. (23) 656-657.

### ***Can a Grid be a node?***

Linking health centres forms a *research grid*.

NOSM has begun to link together various health and science regions together within Northern Ontario. This distance has traditionally been viewed as a disadvantage can be now be viewed as an opportunity to bring together resources in a de-centralized manner in order to gain the critical mass required to compete within the global arena. Linking these de-centralized groups together will form a research grid. This overarching strategy or framework focuses on activities that occur over greater distances. Importantly, this distance becomes a competitive advantage to be exploited. Research and innovation can be driven to solve specific needs within Northern Ontario but will have a global impact by providing a benchmark for other communities and regions with similar challenges and objectives.

For example, the creation of specialized products or research projects that solve local needs for the North enables rapid expansion to other areas that are similar but lack the critical mass to develop their own solutions. Thus the dispersed nature of the North creates opportunities if the focus is on projects that solve local needs.

Linking the research grid into international research hubs ensures global impact.

With the global role-out of telecommunications infrastructure, the ability to conduct research and deliver healthcare in an innovative manner will be a greater market need. NOSM can facilitate the linking of Northern Ontario research groups into a structured grid. This grid will aid in bringing together the critical mass required to develop the innovation necessary to not only compete globally but work collaboratively in the international arena. The grid acts as a node focused on addressing local issues that are dispersed throughout the grid system. This node will need to be linked into a global hub to showcase its area of specialty and ensure that it has global impact.

## **Three Strategic Plans: Building a Health Research Economy Utilizing the Grid**

### **I. Clinical Health Research Strategy**

This strategy consists of four initiatives, which are listed below. Each of these initiatives is then described in detail in this section.

1. Northern Ontario/Canadian Hospital Research Strategy
2. Community-based Health Research Network
3. First Nations Health Research Network
4. Ethics Review Boards – Agreed Standards & Mutual Recognition

#### **1. Northern Ontario/Canadian Hospital Research Initiative**

*Short term (immediate) initiative*

##### **Summary**

Clinical health care delivery and health research activities in Northern Ontario are removed geographically from those occurring in major urban centres. For this reason, it has been difficult to recruit highly qualified medical, research, and technical support staff to Northern Ontario, including those in the industrial and capital sourcing industry, which in turn impacts significantly on the economic well-being of the region. In addition, the dispersed nature of health care delivery resources in Northern Ontario also results in reduced access to medical care for many people in the region, particularly more remote populations.

Together, these issues constitute historical barriers to the development of effective and efficient health care practices and health sciences research in the Northern Ontario region. The Northern Ontario region is thus in a similar position to many other Canadian jurisdictions which, with the exception of major urban centres, also have dispersed nodes of expertise and populations spread out across large distances.

In September 2005, the new Northern Ontario School of Medicine (NOSM) will begin offering classes for medical students. NOSM is the first medical school in Canada to be built in over 30 years and represents a unique opportunity for training and locating of clinicians and researchers in a rural setting. This program has recruited numerous faculty members and local clinicians, and the intent is to further attract and retain highly qualified clinical, research and technical support personnel.

The inception of NOSM brings new leadership and assets into the regional health science spectrum. This provides Northern Ontario with a significant and unique opportunity to leverage these assets and create synergies among regional clinical, research and health care delivery resources, including industrial and capital source partners, in order to better serve its rural population base and bring a new level of economic vitality to the region.

The inauguration of NOSM therefore presents a unique opportunity for Northern Ontario not only to “reset the clock” on many its historical barriers to

NOSM brings new leadership and assets into the regional health science spectrum, and provides Northern Ontario with a significant and unique opportunity to leverage these assets and create synergies among regional clinical, research and health care delivery resources.

The inauguration of NOSM therefore presents a unique opportunity for Northern Ontario not only to “reset the clock” on many its historical barriers to the development of leading edge health care practices

The CFI programs are intended to highlight strategies such as translational research strategies which are a perfect fit in the Northern Ontario health research strategic plan.

the development of leading edge health care practices and health sciences research in the region, but also to take a strong leadership position in developing a national network of northern/rural hospitals and medical centres with similar challenges and objectives.

In order to capitalize on these potential (and time-sensitive) opportunities, a strategy is required to link new and existing strengths in the region, enhance globally competitive assets, and leverage these opportunities for regional, and potentially pan-Canadian, development and economic growth.

### **A New CFI Funding Initiative**

The Canada Foundation for Innovation (“CFI”) will issue requests for proposals for several major funding initiatives, one of which will be done jointly with the CIHR that can potentially assist the Northern Ontario region in satisfying its health care delivery, research, and economic objectives. These funding initiatives are relevant both to NOSM, for its regional (or pan-Canadian) health care delivery and research strategy, and to individual research hospitals that desire to put their own funding mechanisms and strategic plans into place.

The CFI programs are intended to highlight strategies such as translational research strategies which are a perfect fit in the Northern Ontario Health Research strategic plan. We strongly recommend that the CFI program be endorsed and the application process begins immediately.

The amount of funding projected to be available to Northern Ontario associated with the current round of CFI applications is likely to be in the range \$20-50M, including funds from all appropriate CFI and CIHR initiatives and matching funds from various provincial and private sources.

### **Regional Needs**

There are several current and vital regional needs in Northern Ontario that have the potential to be satisfied by successful CFI funding to a platform of research hospitals in the region. These include:

- Differentiation of Northern Ontario’s research strengths and capabilities in the national and international landscapes;
- Identification and facilitation of unique niche research programs;
- Attainment of a critical mass of health care and research resources through collaboration and partnership;
- Access to specific funds not available to other regions;
- Gains national and international presence in fast growing economic sector;
- Attainment of substantial social outcomes;
- Attainment of better healthcare in remote, marginalized and/or virtual communities;
- Expansion of research links and networks beyond Northern Ontario (especially those with remote access or only virtual links to modern healthcare delivery);
- Renewed emphasis on commercialization of research and clinical outputs;
- Leverage the opportunity to market unique Northern Ontario expertise nationally and internationally; and

- Mitigate distance with excellent telecommunications infrastructure.

## Regional Assets

As already noted above, the establishment of NOSM brings new leadership and assets into the regional health science spectrum. These assets can and should be leveraged in order to create effective and commercially viable synergies among regional clinical, research and health care delivery resources.

The Northern Ontario region hosts several existing health research activities in several broad basic and clinical research areas. These include:

- Population health/public health care research, education and service delivery in a dispersed and rural environment;
- Electronic health information and delivery system, including electronic medical records, videoconferencing and telehealth;
- Diseases/disorders specifically affecting northern populations;
- Occupational health;
- Evaluation of health and health education delivery approaches; and
- Research into healthy aging and health care services delivery in dispersed and rural environments.

## Regional Champions

There are several regional champion organizations and centres that comprise the core resources of Northern Ontario and which will likely represent the basic and potential drivers of any successes and failures NOSM may experience in undertaking CFI-related activities related to dispersed and rural health.

Both The Thunder Bay Regional Health Science Centre and the Sudbury Regional Hospital are key stakeholders that will aid in galvanizing the hospital community across Northern Ontario, and possibly through out Northern Canada, to come together with one initiative. By bridging the NE and NW, these two hospitals will act as a more cohesive unit and aid to draw in more participating hospital groups. Other key champions to facilitate these interactions include:

- Medical school campuses in Sudbury and Thunder Bay (NOSM);
- Laurentian University in Sudbury;
- Lakehead University in Thunder Bay;
- Centres for Rural and Northern Health Research in Sudbury and Thunder Bay;
- Centre of Excellence for Children and Adolescents with Special Needs in Thunder Bay;
- Centre for Healthcare Ethics in Thunder Bay;
- Northern Educational Centre for Aging and Health in Thunder Bay;
- Great Lakes Forestry Centre and Ontario Forest Research Institute in Sault Ste. Marie; and
- Aboriginal medicine organizations and health care delivery centres.

Strong leadership and local champions will be core drivers of success.

## Regional Stakeholders

As with champions, there are several regional stakeholder health care delivery hospitals, centres and organizations that will additionally comprise the core resources, recipients and influencers of NOSM's CFI-related activities relating to dispersed and rural health care delivery and research. These include:

- Hospitals and health care delivery centres that choose to be part of the NOSM-led rural health care delivery and research network. Possible stakeholder partners include:
  - Thunder Bay Regional Health Sciences Centre;
  - Northwestern Ontario Regional Cancer Centre;
  - Sudbury Regional Hospital;
  - Northeastern Ontario Regional Cancer Centre;
  - Sault Area Hospital;
  - North Bay General Hospital;
  - Algoma Regional Cancer Centre;
  - Timmins and District Hospital; and
  - Other northern or rural hospitals and health care centres across Canada.
- Researchers in rural medicine attached to universities and working with these centres and hospitals;
- Municipal governments and municipal associations in Northern Ontario; and
- Local, regional, provincial, federal and international funding agencies and capital sources.

## Infrastructure Gaps

There are significant infrastructural and human resource assets in Northern Ontario. However, these resources are located physically far apart. In the past, this has been an obstacle to collaboration and the development of more formal partnerships. In addition, the region is perceived to be remote and far away from many potential collaboration partners in Southern Ontario or elsewhere in Canada.

To this end, Northern Ontario is in the process of investing heavily in communication infrastructure to overcome distance. This wise investment needs to be expanded and capitalized upon to collaborate over distance using both established and cutting edge information and telecommunications technologies, including fibre optic and satellite communications networks, videoconferencing, teleconferencing, electronic/remote surgery portals, internet, e-mail etc.

Generally, the largest infrastructure gaps relate to regional health care delivery and research capacity, and the lack partnership and communication between dispersed existing nodes of such resources in Northern Ontario (e.g., stakeholders). Known gaps include highly qualified personnel, buildings and office space to house them, information and telecommunications infrastructure, clinical and research lab space and equipment, salary support and operating costs.

Bolstering infrastructure and human resource capacity would position NOSM and participating consortium hospitals competitively, both nationally and internationally.

These resources are required in order to gain a critical mass of infrastructure, human, and capital resources in Northern Ontario. Bolstering infrastructure and human resource capacity in these areas would position NOSM and participating consortium hospitals competitively, both nationally and internationally, not only as a leader and best practices benchmark for provision of rural health care delivery services and research, but also for strong leadership in developing best practices relating to commercialization of innovative technologies in a rural and dispersed environment.

### Infrastructure Rationale and Need

The CFI proposed strategy stems from the concept that the success of a community or an organization depends on its ability to exploit its core assets and strengths and leverage these in order to obtain funding to best bridge relevant gaps.

The focus of the CFI ask document will likely be on leveraging existing clinical research activities that have reached a certain momentum in Northern Ontario such as rural medicine research and health care delivery, accessing remote or marginalized groups, clinical trials over large distances, development community-based medical programs, accessing virtual communities, to name a few. Focus was also targeted at activities that have commercial potential or exportability.

The focus of this strategy comprises empowering current stakeholders in clinical research, by bringing them together and providing infrastructures that are needed to establish themselves as competitive players in the national and global market. For this Northern Ontario/Canadian, rural or remote Clinical Study Initiative the following initiatives are envisioned.

- Creation of Northern Ontario/Canadian Clinical Study Association;
- Meta-electronic patient registry for the whole Northern Ontario;
- Fund for multidisciplinary and collaborative research on strategic themes;
- Research program on best practices in telemedicine, with the goal of spreading the technology and its use among Northern Ontario communities;
- Program on Rural Health Economics;

A second component of the CFI proposed strategy comprises commercialization enablers, and associated infrastructural requirements, for the region. This will be a particularly important aspect of the CFI application, as competition for funding will be significant, and Northern Ontario has had several excellent examples of commercialization of basic research on which to draw in its competitive positioning.

The primary infrastructural need for Northern Ontario is a community-based clinical research institute. This would comprise a network of researchers, with associated local or regional infrastructure, which would link all participating hospitals in Northern Ontario or, potentially, all participating northern/rural hospitals and medical centres across Canada. In either scenario, NOSM and the two regional hospitals would be the focal point of a pan-Northern, or pan-Canadian, hub and node network model for rural health care delivery and research.

The focus of the CFI strategy is to empower current stakeholders and exploit existing resources for health care delivery, research and commercialization purposes.

The primary infrastructural need for Northern Ontario is a community-based clinical research institute, comprising a network of researchers, with associated local or regional infrastructure.

The focus of the initiative would be on local health outcomes/clinical outcomes research of specific therapeutic approaches, including activities relating to:

- Efficient utilization of electronic patient databases and other information and telecommunications technologies;
- Development of virtual health care delivery and research communities;
- Community medicine with a focus on underserved communities and marginalized groups e.g., First Nations, remote populations, other; and
- Epidemiological studies of diseases specific to, or of greater prevalence, in Northern Ontario.

### Overview of CFI Infrastructure and Capital Sourcing Opportunities

The CFI will issue a draft call for proposals and a final call in November 2005 for two major funding initiatives, comprising two different funds each, which can potentially assist the region in satisfying its health care delivery, research, economic and commercialization objectives.

- An **Infrastructure Fund** for basic research. It has been discussed that this fund is to be divided into two funds; a Leading Edge Fund for reinvesting in existing CFI-funded infrastructure and a New Initiatives Fund for new infrastructure. The total fund is estimated to be approximately \$300-\$350M; and
- A **Research Hospital Fund** for clinical research. It has been discussed that this fund is also to be divided into two components. The first is a macro Clinical Research Initiative fund of approximately \$100-\$150M, which will see the establishment of ~6 centres or consortia of clinical research excellence uniting all major hospitals in a given urban centre. The unique proposition for the Clinical Research Initiative fund is that it may be supported by matching operational funds from CIHR. The second fund is a proposed \$300M Research Hospital Fund for individual healthcare centres pursuing high-profile initiatives in translational research.

All four funds have similar deadlines. In order to realize these opportunities, individual hospitals or hospital consortia will have to craft a focused, value-added translational research strategy, affect widespread organizational buy-in, craft well-developed research and clinical strategies, and assemble partners before preparing CFI applications. Key success factors in these competitions will be:

- A research strategy that is integrated with the clinical sphere and focuses decisively on research translation and commercialization;
- A program that is unique within Canada and positions the organization for globally competitive thought leadership;
- A novel research focus that is dependent on the acquisition of major new infrastructure;
- An infrastructure and financial strategy that builds on previous investments in infrastructure (i.e. by CFI); and
- Use of alternative financing mechanisms to secure matching funds.

The strategic rationale and infrastructural, human and capital resource requirements needed to position NOSM to satisfy its clinical, research and economic objectives have been outlined above.

### Success Factors

Perhaps the most important factor for successful implementation of NOSM's CFI strategy will be increasing the degree and impact of partnership activities between geographically dispersed resource nodes. Indeed, many other potential success factors are encompassed by the partnership issue. For example, partnership is the most efficient manner in which NOSM can gain critical mass in resources and expertise, which in turn will facilitate economic initiatives and growth in the region. Moreover, effective partnering will also allow optimal leveraging of existing resources within Northern Ontario, open channels of communication between Northern Ontario and other global resource locations, allow Northern Ontario to remain current with regard to information, telecommunication, clinical and research best practices, and reduce negative perceptions about collaborating with partners over distance.

As implied above, partnering as a potential fulcrum of success applies not only to partnership activities within Northern Ontario, but also between Northern Ontario and other resource locations in Canada and elsewhere. Partnering opportunities within Northern Ontario include, but are not limited to:

- Medical school campuses in Sudbury and Thunder Bay (NOSM);
- Laurentian University in Sudbury;
- Lakehead University in Thunder Bay;
- Algoma University in Sault Ste. Marie;
- Nipissing University in North Bay;
- Confederation College in Thunder Bay;
- Centres for Rural and Northern Health Research in Sudbury and Thunder Bay;
- Centre of Excellence for Children and Adolescents with Special Needs in Thunder Bay;
- Centre for Healthcare Ethics in Thunder Bay;
- Northern Educational Centre for Aging and Health in Thunder Bay;
- Great Lakes Forestry Centre and Ontario Forest Research Institute in Sault Ste. Marie;
- Aboriginal medicine organizations and health care delivery centres;
- Thunder Bay Regional Health Sciences Centre;
- Northwestern Ontario Regional Cancer Centre;
- Sudbury Regional Hospital;
- Northeastern Ontario Cancer Centre;
- Sault Area Hospital;
- North Bay General Hospital;
- Algoma Regional Cancer Centre;
- Timmins and District Hospital; and
- Other northern or rural hospitals and health care centres across Canada;
- Researchers in rural medicine attached to universities and working with these centres and hospitals;
- Local and regional industrial partners;
- Local and regional capital sources;

- Local and regional technology transfer offices, centres, networks and organizations;
- Municipal and regional governments and city councils in Northern Ontario;
- Local and regional philanthropic sources; and
- Local and regional funding agencies and sources.

Partnering opportunities outside of Northern Ontario include, but are not limited to:

- Provincial and national governments;
- Provincial, national and international funding agencies and sources;
- Provincial, national and international philanthropic sources;
- Provincial, national and international technology transfer offices, centres, networks and organizations;
- Provincial, national and international industrial partners; and
- Provincial, national and international capital sources.

Specific partnering opportunities relative to existing and future foreseeable rural and dispersed health care delivery and research resources within Northern Ontario include, but are not limited to:

- Large diagnostics firms for development and marketing of research for diagnostics tests;
- Pharmaceutical companies for bio-prospecting and to offer research services such as screening of drugs against unique cell lines developed in Northern Ontario;
- The Bay Crest Centre, particularly the Rotman Research Institute – aging research;
- Working with workplace safety and insurance board (WSIB) and large industries such as mining and forestry for occupational health research ;
- Biotechnology or large pharmaceutical firms to invest into selected research programs for right of first refusal;
- Large pharmaceutical firms for clinical trials ;
- Working with geography departments (GIS) to develop:
  - maps of health care services
  - epidemiology
  - maps of bio-prospecting
- Working with economics departments for health outcomes research;
- Using databases like Group Health for rapid selection of patients for therapeutic research (not just clinical drug trials);
- Working with software developers to develop specialized programs for wait times etc.;
- Partnering with suppliers of telehealth equipment for researching applications best practice;
- Offering of research service capacity to larger centres in Canada and US; and,
- Build up access to research funding needed for research programs through partnerships with major funding agencies and philanthropic foundations to obtain dedicated funds. Possibilities include:
  - Canadian Institute for Health Research (CIHR)
  - Canadian Health Services Research Foundation (CHSRF)
  - Health foundations

- Philanthropic family foundations such as Rockefeller, Gates etc.

Networking and collaboration is a way to achieve critical mass for research, funding and financing purposes.

## Risks

There are several risks entailed in the approach advocated. One such risk is Northern Ontario clinicians and researchers receiving due notice in a competitive research funding environment which has traditionally favoured large urban centres where resources have reached critical mass. Northern Ontario will need to focus on specific areas of strength to become competitive and remain that way. With health research clusters being developed in many less urban centers, niche areas of expertise are becoming more competitive for resources and intellectual capital. Networking and collaboration is a way to achieve critical mass for research, funding and financing purposes.

A second risk is that Northern Ontario's health research assets are physically dispersed. In the past, this has been an obstacle to collaboration. Failure to collaborate leads to duplication of services, wasted use of limited human and capital resources and less emphasis on basic research. However, the region has invested heavily in communication infrastructure to overcome distance, providing an excellent portal for increased partnerships and collaborations.

In particular, NOSM may not be able to put forth a competitive bid if it cannot secure support from all or a significant number of hospitals in the region. Similarly, if NOSM desires to pursue a pan-Canadian network strategy, success will depend on buy-in from hospitals outside of Northern Ontario. This partnering risk can be mitigated by a clear articulation of NOSM's Northern Ontario/Canadian strategy and the benefits to participating hospitals and medical centres of being involved in the initiative.

A third risk is the negative perception about distance from other centres, including those in Southern Ontario. The marketing message delivered through the Internet and at every opportunity should emphasize that many of the centres in the region are reachable in less time than it takes to travel between some of the major centres in Southern Ontario and that they are further South than Vancouver, Seattle and other large centres.

A fourth risk is that commercialization of health research is a new area for Northern Ontario. Nevertheless, partnering with more senior and experienced academic and industrial partners will help to substantially mitigate any risks involved, including establishing regional venture capital funds. This includes accessible services for intellectual property management, accessible technology transfer specialists, physical infrastructure, capital, a good supply of skilled personnel and original innovative research. In addition, the fact that high level research is already conducted in the region and three successful companies have already spun out from universities in Northern Ontario also mitigates the risk of engaging in commercialization activities from a more rural perspective.

A final risk is presented by the competitive landscape. Many consortia and individual hospitals will be applying for CFI funding, and success will depend strongly on an understanding of how other regional centers position themselves competitively and how NOSM can distinguish itself from its competitors as a unique value proposition.

Success will depend on how NOSM can distinguish itself from its competitors as a unique value proposition.

## Action Plan, Milestones and Timelines

Tables 1 and 2 infra comprise a suggested 15 month action plan geared to prepare NOSM for the upcoming round of CFI funding, including both Research Hospital Funds and both Infrastructure Funds, complete with milestones. As indicated in the two spreadsheets below, the action plan is comprised of three phases:

Tables 1 & 2 are a 15 month action plan. CFI-imposed deadlines indicate clearly that “time is of the essence”.

- Phase I: Creation of a strategic roadmap for CFI application;
  - Creation of business case
  - Identification of Northern Ontario/Canadian participating hospitals
  - Conduct benchmarking
  - Creation of strategic plan
- Phase II: Develop and submit LOI; and
- Phase III: Develop and submit full application.

It is clear from the amount of preparation required relevant to the projected CFI deadlines that time is of the essence. The call for proposals will be made by CFI in mid-November 2005 and the letter of intent (“LOI”) is due in February 2006. Consequently, prior to January 2006, the creation of a strategic roadmap, identification of participating Northern Ontario/Canadian hospitals, and creation of the strategy for the LOI (informed by the strategy for the full application) must be undertaken i.e., all of these steps must be completed in 3-4 months.

The urgency for preparing for these deadlines will be compounded to the degree that NOSM, and its affiliated hospitals and universities, may wish to apply for more than one of the four available CFI funds. A more detailed action plan up to submission of the LOI is shown in Table 1 below.

**Table 1. Action Plan up to Submission of LOI**

Northern Ontario: CFI and Associated Work plans	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr
	15 31	15 31	15 30	15 31	15 30	15 31	15 31	15 28	15 31
<b>PHASE I</b>									
<b>Project 1: Creation of strategic roadmap for CFI application</b>									
Expand business case for CFI from N.O. HR&I Strategy report for Northern Ontario groups and/or virtual communities) to identify gaps, under serviced needs and to identify projects									
Create hospital and community search criteria with NOSM to determine type of participating groups									
Convene meeting of stakeholders to create and refine operating model									
<b>Deliverable: Expanded Business Case + high level operating model</b>									
<b>Project 2: Identification of Northern Ontario/Canadian Participating Institutions</b>									
Expand and validate operating model									
Create framework to identify Northern Canadian hospital partnerships									
Prioritize key stakeholder list									
Support consensus building activities by developing supporting materials, such as word documents or PowerPoint presentations, in support of institutional research vision									
Validate findings and supporting material with NOSM									
Contact key hospitals outside of Northern Ontario									
Facilitate meetings (2 to 3) with stakeholder groups to assess opportunities and gaps									
<b>Deliverable: Concise report on likely participants, opportunities and gaps</b>									
<b>Project 3: Benchmarking International Research Consortia</b>									
Create a list of 5-10 benchmark sites									
Create prioritization criteria and validate with NOSM									
Identify 2-3 top international or national benchmark sites									
Identify and contact key personnel at each site and set up interviews									
Conduct interviews to benchmark sites									
<b>Benchmark report with recommendations</b>									
<b>Project 4: Framing strategy for Phase II based on Projects 1-3 and LOI announcement</b>									
Create framing document and work plan to guide the internal development of the application; this will be critically informed by the Call for Proposals to be issued by CFI/CIHR in mid-November									
<b>PHASE II</b>									
<b>Project 4: Develop and submit LOI</b>									
Create draft strategic plan based on benchmarks and stakeholder consultation									
Facilitate meeting with stakeholders to review, revise and validate strategic plan									
Translate strategic research and infrastructure plan into implementation model									
Establish working groups and provide project management support (estimate based on pan-Northern Canada participation)									
Liaise with senior leadership/strategy caucus									
Write key sections of project outline									
Review and finalize application									

It is important to recall that the LOI is an adjudicated application reviewed by the CFI and/or CIHR. Invitations to submit full applications are projected to be released in the spring of 2006, with full applications due in December 2006. As such, there is a “dead zone” between submission of the adjudicated LOI and invitations by the CFI to submit a full proposal, as indicated by the grey box in Table 2 below.

Individual hospitals may leverage the work associated with the CFI proposal by undertaking their own strategic planning process for translational research during this period of time in order to secure funding from the CFI Research Hospital Fund. These individual projects could occur during (or prior to) the period between the submission of the LOI and the receipt of invitations for application (between February and the spring). A detailed action plan

covering the period from submission of the LOI to submission of the full application is given in Table 2.

**Table 2. Action Plan from LOI to Submission of Full Application**

Northern Ontario: CFI and Associated Work plans		Feb		Mar		Apr		May		Jun		Jul		Aug		Sep		Oct		Nov	
		15	31	15	28	15	31	15	30	15	31	15	30	15	31	15	31	15	31	15	31
<b>PHASE III</b>																					
<b>Project 5: CFI - Write up of final application</b>																					
Facilitate meeting with senior leadership from partners across Northern Ontario/Canada																					
Distill outcomes into high-level strategic objectives and implementation model																					
Review, revise and validate objectives/model with senior leadership																					
Disseminate proposed strategic objectives to key stakeholders for comment and revision																					
Convene meeting of senior leadership to finalize objectives and proceed to detailed planning																					
Translate strategic research and infrastructure plan into detailed work plan																					
Establish working groups and provide project management support																					
Liaise with senior leadership/strategy caucus																					
Review and finalize main points and strategy for application																					
Write key sections of application																					
Review and finalize application																					
Expected period between review of CFI LOI and invitation to submit full proposal.																					
Hospitals could undertake their individual research strategies																					

A regional clinical health research network will answer clinical questions relevant to Northern Ontario, while positioning the region well to participate in clinical research.

The vision is for a world-class community-based networked clinical health research originating in Northern Ontario.

## 2. Community-based Health Research Network Initiative

*Mid-term initiative*

### Summary

This initiative focuses on community-based clinical health research, which will be highly inclusive of centres in Northern Ontario and will give an opportunity for practising clinicians such as physicians, nurses, therapists and pharmacists to participate in research.

A clinical health research network of this type is particularly relevant to the grid strategy as it would have a central core with several other points of presence in the main centres in Northern Ontario. Its scope and reach would be across the region and would specialize in conducting and teaching methodology for clinical research across multiple, geographically dispersed centres of clinical care. There would be a strong focus on research into clinical outcomes to modify delivery management approaches to achieve improvements in this. Some work of this nature has already been undertaken in Northern Ontario and proposed projects will build considerably on these existing resources.

A clinic of health research network of the type described above will answer clinical questions relevant to Northern Ontario, while positioning the region well to participate in clinical research. There is a strong shift in funding towards this type of research in Canada.

The concept would link NOSM with all the main centres across Northern Ontario and would have a clinical hub linked with the Group Health Centre in Sault Ste Marie as the largest of its kind in Canada.

Additional infrastructure will be needed for this in the major centres in Northern Ontario. There are a number of sources of possible funding for this, including the CFI New Initiatives fund and the cities where it would be located.

### Vision

World-class community-based networked clinical health research originating in Northern Ontario

### Mission

The mission of such a networked institution must ultimately be defined by those who will build it up and run it.

- To conduct world-class clinical research in the geographically dispersed and remote clinical environments present in Northern Ontario.
- To build up a research culture that is integral with clinical practice in Northern Ontario.
- To educate and spread clinical research methodology within the region.

- To publish the results of clinical research to raise the profile and standing of the healthcare community in Northern Ontario.

## The Market Need

There is a strong shift towards clinical research funding in Canada that fill unique niches or market needs.

Northern Ontario has not up to now been well positioned to undertake original clinical research. In particular, few practicing physicians have been able to participate in original research, particularly outcomes research to measure the clinical and cost effectiveness of healthcare delivery and to modify and improve it according to the findings. Having the capacity to do so results in better clinical outcomes for patients and often achieves cost savings to the health system at the same time.

Additionally, there is a strong shift towards clinical research in the funding of health research in Canada. The creation of this type of research body would position Northern Ontario to benefit from this shift in research funding. In particular, research projects that would span the entire geographical region of Northern Ontario would have unique and strong impact and present as strong attractors of funding.

It is important to define what is meant by the terminology used in this initiative. The term “Community-based” means that it will offer the opportunity for clinicians who are currently engaged in practice to participate in research. “Clinical” in this context refers to research that involves human subjects. This distinguishes it from laboratory research. This research area is not synonymous with clinical drug trials. The term “clinician” refers to professionals who work with patients, namely physicians, registered nurses, therapists, nurse practitioners, pharmacists, etc.

## Background

### *Objectives*

The term “Community-based” means that it will offer the opportunity for clinicians who are currently engaged in practice to participate in research.

This clinical health research network would greatly enhance the clinical research capacity of Northern Ontario. In addition to conducting clinical research, this health research network would also partner with the medical school to train students and, in the future, residents in clinical research methodology. This would fit well with the educational mission of NOSM.

It would also provide clinical professionals in Northern Ontario unprecedented access to stimulating research opportunities to enrich professional practice. This will contribute strongly to professional satisfaction of clinical practitioners in the region, which assists in recruitment and retention, providing an additional positive impact on health care delivery in the region.

This research network will become a focal point for many aspects of clinical research, concentrating on those which are of critical relevance to Northern Ontario residents. A majority of residents of Canada share clinical issues that are important to Northern Ontario. Therefore, good research done in the region will raise its profile and it has the potential to become a major provider of evidence-based practice and to develop policy that is applicable nationally.

## Strategy

NOSM will have the key role of championing this initiative.

### Roles and responsibilities

The key players in this research network are envisaged to be:

1. NOSM in Thunder Bay and Sudbury.
2. Group Health Centre (GHC) in Sault Ste Marie
3. Satellite facilities (to be created) in other centres such as Timmins, North Bay, Dryden and Kenora.
4. Local governments (city authorities) in each of the cities where these facilities will be situated.

NOSM will have the key role of championing this initiative and kicking it off with initial discussions with GHC and the first few potential funders.

As soon as a joint task team has been formed (or even initial dialogue is initiated between these two leading parties), then both NOSM and GHC will be approaching important stakeholders for support, including the city council of Sault Ste Marie.

A major responsibility of the core research facility will be to drive a culture and publishing the research findings of the network. With good quality research output, this research network should see even more jobs created.

The task team drawn from these initial players will then need to identify potential partners in clinical practice in the other centres with a view to enlisting them on the team. With those local champions in each centre, it will be the task team's responsibility to approach those city authorities too for possible support, which will provide the seed for other matched funding.

Research will be led from the hub facility or institute, which would have key researchers who will be part of the NOSM faculty. One of the task team's responsibilities will be to find a director of this research facility, who will then take the ultimate leadership role to drive the project forward.

A major responsibility of the core research facility will be to drive a fertile culture, including publishing the research findings of the network. A lack of publication in peer reviewed journals in the past has resulted in under-recognition of the work done at the GHC, for example. Publication and recognition translate into better funding.

The satellite facilities will be points of presence for the gathering of data and dissemination back of findings and best practice resulting from the research. They may also conduct some smaller projects that answer very locale-specific questions. However, the emphasis should remain on multi-centre projects that give answers applicable throughout the region and in many other areas of Canada. This will ensure critical mass for the size and applicability of the work done, which will also ensure good funding into the future.

### Human resources

The detailed business planning which will have to be undertaken in the course of setting up an institute, which will ultimately form the hub of this research network, will define human resources requirements in more detail. Over the initial five years, they are estimated to include:

- A director of the research hub: 1
- Principle investigators at the hub and at satellite sites: 12
- Research assistants at the hub and at satellite sites: 36
- Support staff, mostly at the hub, but also some at satellite sites: 12

Over the next decade, with good quality research output, this research network could attract funding that would see even more jobs created.

Participation will be open to all qualified professionals with an interest in clinical research in the region, with strong participation anticipated from those who are on the faculty of the medical school.

#### Infrastructure, equipment & systems

Physical building space will be needed to conduct research. This will include space in which patients can consult or undergo tests, as well as space for the researchers to work in and to house equipment.

Examples of the requirements would include:

- Clinical laboratory space, including interview facilities and examination rooms.
- Information technology infrastructure.
- Teaching facilities, including videoconferencing that will link this hub with the existing videoconference-linked twin campuses of the medical school.
- Office space for the director and management personnel of the research network.
- Space for support personnel, researchers, visiting scientists and post-graduate students.

A greater level of detail should be defined as part of the detailed business planning that will be needed prior to fundraising as described in the “next steps” section to guide implementation.

## Reward System

There are several rewards in the successful creation of this research grid:

For NOSM, there is the reward of recognition of the quality of the school, thus increasing its standing, which will lead to better funding.

For GHC in Sault Ste Marie there is the reward of recognition of the quality of the centre’s research activities, which are less recognized at this time than the excellence of its model of healthcare delivery. There is also the reward of an additional facility for research, which is likely to provide, simultaneously, some additional options and quality of care for patients.

For individual researchers and clinicians there is the reward of career progression due to increased skills and strengthened experience. There is also the reward of the intellectual stimulation of participating in research rather than purely delivering healthcare, which can become repetitive and routine. Research can be interesting and a lot of fun!

Physical building space will be needed to conduct research.

There are rewards for multiple stakeholders in the successful creation of this research grid.

For the local government (city authorities) in each of the cities where these facilities will be sited, bringing in a presence linked with the medical school and thus increased and improved healthcare delivery is extremely important to the social fabric of the community.

## Regional Assets

There are a number of key regional assets that will enhance this networked institution and provide many of the building blocks for its creation.

It will also be important for this initiative to have strong champions and advocates for its creation. These are present at NOSM and GHC.

Other key stakeholders in the region include clinical practitioner groups and associations as well as the hospitals located in Thunder Bay, Sudbury, Sault Ste Marie, Timmins, North Bay, Dryden and Kenora.

The key assets to act as the catalysts to enable this type of research to be developed include the medical school, which will be training new physicians and can include training in community-based clinical research and its importance within the curriculum of undergraduate and, in the future, post-graduate students. The presence of scientists at the school will be an asset as well in training future highly qualified personnel to participate in research with this Health Research Network.

The Group Health Centre (GHC) is another core regional asset, which would make a logical hub for a community-based clinical research undertaking. The GHC already has many components in place for it to be the hub of a unique research initiative that would be a national asset. It is already the largest health delivery vehicle of its kind in Canada and has a large electronic database of the order of 60,000 patients.

This large number of patients receiving primary care on one system makes it easy to enter and track patient information contributed by multiple clinical practitioners working in a team trialing new treatment protocols. Most importantly, it makes it very feasible to measure changes in outcomes as a result of changes in management of diseases, while fully preserving the patients' absolute right to confidentiality at all times. Chronic disease site registries have been created, enabling the trialing of improved interventions in patients with the most debilitating and costly burden of disease.

This centre, as well as being a large deliverer of care in Canada, has a track record of having undertaken initiatives that take information from the literature and adapt practice to the specific needs of its environment. This has allowed for implementation of new treatment approaches and measurement of outcomes. This approach is at the heart of community-based clinical health research.

Examples of community-based clinical research at GHC include:

- The Health Promotion Initiative for Diabetes (HPID) project.
- The Vascular Intervention Project (VIP).
- The Congestive Heart Failure Discharge Transition project.
- The Anti-coagulation Clinic project.

The Group Health Centre is a core regional asset for this initiative.

Chronic disease site registries have been created, enabling the trialing of improved interventions in patients with the most debilitating and costly burden of disease.

Importantly, the improved clinical outcomes for patients have been quantified along with the cost-savings to the health system, freeing up resources which can be spent on other patients or diseases. For example, a 68% decrease in the re-admission rate for congestive heart failure patients at the Sault Area Hospital was measured following the analysis of reasons for readmission, followed by the development and implementation of a new approach to the management of these patients after discharge from hospital.

The database paves the way for studies in genomics and proteomics.

The database of patients with specific diseases is focused on Primary Care and is Population-based. This contains real patient data and family registries. This paves the way for studies in genomics and proteomics that would link well with the proposed proteomics and genomics work that is proposed elsewhere in this document.

Gene-environment interactions studies could also be undertaken and the GHC is a participant in the multi-centre Cardiogene study.

The completeness of the records of patients at the GHC also facilitate long-term follow-up of sizable cohorts of patients to measure outcomes.

Another research group that should be consulted to link with the Clinical research network during the more detailed business planning that will be needed is the Centre for Rural and Northern Health Research.

### **Infrastructure Gaps and Resources Needed**

In order to build capacity in Northern Ontario for community-based clinical research, additional infrastructure will be needed in the region.

A hub will be needed from which to run the research programs of the clinical health research network. It is recommended that this hub should be located in Sault Ste Marie, which already has demonstrated capacity for originating its own clinical research as well as in collaborating with larger research initiatives.

Smaller satellite facilities will be located in other communities in Northern Ontario, such as Kenora, Dryden, Timmins, North Bay, Thunder Bay and Sudbury. These would be established in phases. They will be built in partnership with the communities in which they will be located.

The optimum sites for these facilities will vary depending on the size of the community and the existing health centres in those communities. (sites could include annexes to hospitals, clinics, or other health centers), and will include office and visitor space, facilities for research and research support staff, interview suites, IT, etc.

Satellite facilities will be located in communities such as Kenora, Dryden, Timmins, North Bay, Thunder Bay and Sudbury.

It is suggested that the hub of this network, which may ultimately be referred to as an institute, would be a building co-located with GHC in Sault Ste Marie. The other requirement will be human resources as detailed in the strategy above.

This would house a world-class clinical research facility in Sault Ste Marie. The precise requirements, including detailed equipment needs, exact space needs, layout etc would have to be analyzed in a detailed feasibility study and business planning exercise. The detailed business planning which will have to be undertaken in the course of setting up an institute, which will

ultimately form the hub of this research network, will define human resources requirements in more detail. Over the initial five years, they will likely include:

- A director of the research hub: 1
- Principle investigators at the hub and at satellite sites: 12
- Research assistants at the hub and at satellite sites: 36
- Support staff, mostly at the hub, but also some at satellite sites: 12

Over the next decade, with good quality research output, this research network could attract funding that would see even more jobs created.

## Financial Strategy

Given the importance of the community-based clinical research initiative for the medical school and the two universities, the school could apply for a Canada Research Chair to cover the salary of the Director of the Institute that will form the hub. This research will be of national significance and, with the rural and dispersed orientation; it will be concentrating on an area that will make it unlike anything else in Canada. The Canada Research Chairs Program offers funding to universities to appoint outstanding researchers for senior professorships in areas that are aligned with the institution's strategic directions. It is the university that nominates researchers for a chair application and the nominees submit essential personal application information. There are two types of chairs: Tier 1 Chairs, for outstanding researchers that are world leaders in their fields (\$200,000 annually for seven years), and Tier 2 Chairs, for exceptional emerging researchers (\$100,000 annually for five years). Chairs are for full-time appointments. Naturally, a suitable candidate would have to be identified first to undertake such an application.

This initiative would be competitive for infrastructure funding through a CFI new initiative application. This is an initiative that is multidisciplinary and multi-institutional, and that builds research capacity and creates a platform that can be leveraged for future initiatives.

The CFI New Initiative Funds aims at applications that have not been previously supported by the CFI and that promote world-class and innovative research beyond the means of Canadian institutions; initiatives that are linked to new ideas, to different and better ways of performing research, and that capitalize on excellent research, build networks and partnerships. Initiatives should also attract and retain excellent researchers, generate socioeconomic benefits for Canada and lead to improvements to society and quality of life. This initiative would fit all these criteria.

Applications will be due on February 13, 2006 and funding decisions rendered in fall 2006 and letters of intent need to be submitted this fall. As for previous rounds of funding, CFI will fund 40% of eligible costs. Furthermore, if this initiative is successful in applying for funding, it will be eligible for the infrastructure operating fund, and can potentially fund operation to up to 30% of the funding award.

Key dates include:

- |                     |  |
|---------------------|--|
| • November 15, 2005 | Notices of Intent                                |
| • February 13, 2006 | Strategic Research Plan Summary and Applications |
| • November 2006     | Board Decisions                                  |

This initiative would be competitive for infrastructure funding through a CFI new initiative application.

CFI seeks to fund initiatives that are linked to new ideas, to different and better ways of performing research, and that capitalize on excellent research, build networks and partnerships.

Additional matching funds would have to be sought within Northern Ontario. Northern Ontario Heritage Fund Corporation may be a possibility. However, some municipal funding may also be possible.

One concept that could be explored for this initiative is that of City Mortgages.

One concept that could be explored for this, also, is that of City Mortgages. In December 2004, Edmonton City Council allowed its Economic Development Corporation (EDC) to borrow \$8 million in order to build a wet lab facility. If appropriate, and economically feasible, Northern Ontario city councils could allow their EDCs to borrow monies to inject a higher level of funding towards the development of a health research facility. This would result in more upfront investment with less impact on public funds in the short term because this investment would be paid off over time.

Some examples of this type of upfront funding and repayment terms are illustrated in Table 3 below:

**Table 3. Funding and Repayment Terms**

Upfront Investment (Mortgage amount)	Term (years)	Assumed Interest Rate	Annual Payment made by City	Assumed Interest Rate	Annual Payment made by City
\$2,000,000	15	7%	\$214,379.90	5%	\$189,790.40
\$2,000,000	10	7%	\$277,425.60	5%	\$254,557.20
\$1,000,000	15	7%	\$107,189.90	5%	\$ 94,895.28
\$1,000,000	10	7%	\$138,712.80	5%	\$127,278.60
\$3,000,000	15	7%	\$323,578.20	5%	\$284,685.70

The strength of these research initiatives is that they produce improved outcomes and health cost savings, which is a powerful argument for raising funds.

GHC should be involved together with the medical school in any grant applications. They have shown an ability to raise funds for research such as a \$1.5m grant for their Vascular Intervention Program. The strength of the research initiatives they undertake is that they are intended to produce improved outcomes, and often health cost savings, during the research project, which is a powerful argument for raising funds.

Operating grants for discrete projects should be funded by the CIHR and/ or NSERC. The CIHR is the premier health research agency in Canada. It funds research in all areas of health science. Beside traditional research grants, it also provides team grants for large scale projects. The NSERC also provides operational grants, fellowships, and scholarships for university-based research projects including health-focused research. Programs of particular interest at the NSERC would include the Discovery Grants – Northern Research Supplement and the Collaborative Health Research Projects (CHRP).

**Main Steps to Move This Forward**

1. Create a Clinical Research Network/Institute task group. Initially this would primarily consist of individual research champions drawn from the NOSM faculty and GHC. Additional people with a genuine desire and leadership capacity to drive the spread of clinical research within clinical centres in Northern Ontario should be actively sought to join the team to take the initiative as early as possible beyond Sault Ste Marie, Thunder Bay and Sudbury.

Create a Clinical Research Network task group.

2. Appointment of a leader of this initiative as early as possible in year one to drive it forward and manage the project. This must be a person with at least 40% of their time available to dedicate to driving this initiative. There will be a lot of effort needed to bring this to fruition.
3. Identification of existing clinical and research groups willing to participate e.g. existing practices, clinical centres and established research groups doing work that may be relevant to partner, e.g. CRaNHR
4. Detailed inventory of current infrastructure and funding that could potentially attract further matching funds or other leveraging
5. Develop a long term, more detailed vision of the research programs that the Network/Institute will be undertaking
6. Creation and prioritization of a list of pilot projects that would act as a foundation for larger projects in the long term
7. Build this up into a detailed research and business plan for the next 10 years
8. Detailed calculation of budget requirements for infrastructure and operating costs
9. Approach key funding agencies and begin fundraising for capital expenditure and initial operating budgets
10. Fundraising will be an ongoing activity for new research projects
11. If feasible, start 1 to 2 new key pilot projects within some existing space, e.g. using space at GHC or the medical school campuses while the new infrastructure is being put in place
12. Construction of the core facility
13. Construction or refitting of satellite facilities
14. Move into core facility and expand pilot projects into larger projects

### Critical Success Factors and Risks

Pool as much talent as possible and develop critical mass for ground-breaking work.

1. Northern Ontario has comparatively few clinician-researchers at this time and only a handful originating community-based clinical research. To build a large group of nationally and internationally competitive researchers, it will be critical to add to the current few pioneers additional good quality clinicians and researchers while fostering the current drivers and champions.
2. Ability to attract clinicians who wish to undertake research into the research network, to pool as much talent as possible and develop critical mass for larger, groundbreaking work.
3. Ability of the clinical researchers to obtain national and international competitive funds. An internal review process for grant applications with knowledge transfer from successful grant applicants will increase the chance of success.
4. Ensure the participation of stakeholders from numerous groups such as individual communities that will participate in studies and local government to support the creation of the research hub and satellite sites financially.
5. Creation of Northern Ontario/Canadian ethics review systems that will enable various communities, research groups and stakeholders to participate efficiently.

### Milestones and Timeline

**Figure 12. Community-based Health Research Network Initiative Timeline**

Community-based Health Research Network Initiative	Year 1-Q4	Year 2-Q1	Year 2-Q2	Year 2-Q3	Year 2-Q4	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
Create task group.	█												
Appoint initiative leader		█											
Identify clinical and research groups to participate		█											
Detailed inventory: current infrastructure & funding		█	█										
Develop long-term, detailed vision of research programs			█										
Pilot projects listing			█										
Develop detailed research and business plan			█										
Develop detailed budget estimates			█										
Begin fundraising				█	█	█	█	█	█	█	█	█	█
Ongoing fundraising				█	█	█	█	█	█	█	█	█	█
Start key pilot projects					█	█							
Commence construction of core facility						█	█						
Move into core facility							█	█					
Construction / refit of satellite facilities							█	█	█	█			
Scale up of research projects							█	█	█	█	█	█	█

### 3. First Nations Health Research Network Initiative

*Mid-long term initiative*

#### Summary

As a result of social, economic and geographic circumstances aboriginal peoples often have unique healthcare needs.

As a result of social, economic and geographic circumstances, aboriginal peoples often have unique healthcare needs. These needs are served both within the first nation and within non-aboriginal healthcare environments. Often cultural complexities, differences and history has prevented these groups working together to exchange ideas and capabilities that would aid a variety of communities. To bridge these gaps, an area of common ground e.g., a shared resource, would enable stakeholders to come together and exchange ideas. This shared resource could be used as a learning centre, to work on shared research projects, as well as a knowledge exchange centre. The maintenance and governance of such an initiative would be jointly shared by the stakeholders. This centre of common ground is envisioned as a potential gateway between communities where resources can be shared and projects developed.

#### Introduction

One of the challenges that NOSM faces will be to build bridges required to allow for a cultural exchange of ideas and information.

Northern Ontario is comprised of many diverse cultures spreading across a dispersed landscape with rural, urban and remote collections of people. The aboriginal community is one distinct culture that historically inhabits the North. Specifically the aboriginal community has its own socio-economic and health factors that are distinct from other communities. Aboriginal community medicine has a long history that is separate from western medicine practice taught in conventional North American medical schools. This divergence is based on the different approaches to discovery, teaching and practice in a healthcare setting. With such a large gap in the healthcare practices it can appear difficult to work together to solve common problems or learn from each culture.

Each community has health issues unique to its society and environment. These issues can only be solved when all communities work together to solve critical health issues. However, one cannot assume to know the cultural complexities underlying disease etiologies. Before one can investigate this, one must first begin with a *cultural exchange* of ideas, frameworks and history. It is only when cultures begin to understand each other can they begin the next step of working together to develop strategies that will benefit community members.

Just like other communities across Canada, the aboriginal populations across Northern Ontario and Canada are not homogenous in social, economic, cultural or health issues. However, even though these cultures are distinct they do have some common threads within each community. One of the challenges that NOSM faces will be to build bridges required to allow for a cultural exchange of ideas and information.

Addressing aboriginal healthcare needs requires knowledge exchange.

The history of interactions between western and aboriginal medical establishments has not been an interaction of equals. This may contribute to culture divide that remains between these healthcare communities. To aid in overcoming this divide an area of common ground is needed to ensure that all communities can come together, learn about each other and begin to

exchange information. This area of common ground must be based on partnership. In this partnership communities from different backgrounds would work together to build a relationship. This would be based on:

- knowledge exchange
- facilitation of communication
- cultural learning

One of the first steps in facilitating this type of exchange is the creation of an infrastructure that would enable such learning to occur. This infrastructure would be owned, maintained and utilized via equal partnerships by various stakeholders in the healthcare communities. Eventually this partnership is envisioned to encompass healthcare management, delivery and research issues and capacities.

### **The Market Need**

There are many perceived opportunities in healthcare research for aboriginal people to work in partnership with western-based science and medicine. For these partnerships to succeed, both parties must ensure they are being rewarded for their input and that the partnership is truly equal. These rewards could be social, economic or cultural.

### **Background**

#### ***Objectives***

- Creation of common ground that multiple parties can meet to discuss health and research related issues
- Improve community health in Northern Ontario by:
  - education
  - research
  - better healthcare delivery
  - healthcare delivery that is cultural specific
  - development of a model that can be used as a model for other centres in North America
  - enhancement of the capabilities of remote access and dispersed learning

#### ***Strategy***

The aboriginal health research network is designed to bring together diverse and multi-disciplinary stakeholders in Northern Ontario. Key to this the leadership required to unite under one roof. Once this occurs other people within the groups will follow. An example of such an undertaking is the Anishinabek Fisheries Resource Centre<sup>5</sup>. This centre was established as a non-profit entity with equal partnership between native and non-native personnel that serve as an independent source of fisheries information. It carries out research, provides a forum for information sharing and is involved in fisheries management recommendations and conflict resolution. This model serves the

For these partnerships to succeed, both parties must ensure they are being rewarded for their input and that the partnership is truly equal.

Knowledge exchange could occur on an area of common ground equally owned by all stakeholders.

<sup>5</sup> <http://www.aofrc.org>

community and can be used to transfer the lessons learned from fisheries to healthcare management.

#### Roles and responsibilities

- **Board of directors**

This should be comprised of academic leaders, healthcare professionals, scientists, traditional healers and elders. The board should be balanced between native and non-native members with the chair person jointly approved. Treaty 3 and Treaty 8 bands should also have equal representation.

- **Educational directors**

There will be education directors that engage their respective communities to create specialized workshops that will aid in creating specialized educational materials

- **Healthcare directors/liaison**

There will be healthcare directors that understand the needs and requirement of individual communities. Furthermore this director will also work with individual communities in order to facilitate interactions between various groups. It is envisioned that these directors would also have strong links with NOSM and would aid in facilitating interactions with medical students and communities.

- **Research Directors**

These research directors will work with groups such as NOSM and individual aboriginal groups to determine how (or if) these stakeholders what to participate in research activities.

#### Human resources

The need for human resources will be determined based on the final research plan, the scope of the initiative, the number of partners engaged in the project, and the timelines set forth in the plan. The human resource needs should include the following categories:

- Teachers
- Elders
- Students
- Administrative support

#### Infrastructures, equipments, tools & systems

To fully implement this plan, some infrastructure will be required. This would include a structure (or part of one) that has the follow characteristics:

- meeting rooms for workshops
- learning centres where groups of people can come together
- electronic infrastructure to capitalize on video conferencing, remote learning and participate and host electronic conferences

Health, research and education could all occur at this centre.

This infrastructure (or part of one) will be situated outside of Sudbury and Thunder Bay in an area such as Dryden, Sioux Lookout or Timmins.

## Reward System

The dialogue envisioned is that this project should result in tangible community-based programs. These first few programs would be on a small pilot scale and ideally would be used as an example for future programs. Only when both communities were significantly gaining from the programs would this continue to be a success. In creating these programs each group would have an equal part in:

- decision making
- creation of specialized programs
- monitor implementation and aid in continuous improvements
- work with key stakeholders to develop research and training programs that would benefit all groups

## Financial Strategy

### *Year 1*

Participating groups would create a non-profit organization which would contribute \$10,000 to \$25,000 each for a combined project total of \$50,000 to \$100,000. From this a committee could be formed and key opportunities would be identified. These would include:

- learning initiatives
- selection of the location and physical infrastructure site
- short and long term projects

### *Year 2*

Within the second year the committee would source funding to either rent or purchase the infrastructure required to operationalize the strategy. These funding sources could come from:

- For the FY 2005-2006 the Canadian Federal government has announced the:
  - Aboriginal Health Transition Fund (\$200 million over five years)
  - Aboriginal Health Human Resources Initiative (\$100 million over five years)<sup>6</sup>
  - Aboriginal Health Human Resources Initiative (\$100 million) to increase the number of Aboriginal people choosing health care professions and improve the retention of health workers
- FedNor and NOHFC may participate in a consortium of people if there is significant job creation

All stakeholders should contribute to the organization, in kind or monetarily, to ensure proper representation.

<sup>6</sup> [http://www.tbs-sct.gc.ca/est-pre/20052006/HLTH-SANT/HLTH-SANTr5604\\_e.asp](http://www.tbs-sct.gc.ca/est-pre/20052006/HLTH-SANT/HLTH-SANTr5604_e.asp)

In kind contributions from the city or town or a mortgage backed by a city. The city mortgage is detailed below.

**Concept**

In December 2004, Edmonton City Council allowed its Economic Development Corporation to borrow \$8 million in order to build a wet lab facility. If appropriate and economically feasible, Northern Ontario city councils could allow their EDCs to borrow monies to inject a higher level of funding towards the development of the health research strategy. This would result in more upfront investment with less impact on the taxpayers in the short term because this investment would be paid off over time.

There are relevant provisions and/or limitations within the bylaws and/or Ministry of Municipal Affairs but these have not been investigated further to date, which could be pursued in order to secure appropriate funding.

**Terms and Payments**

Some examples of upfront funding and repayment terms are illustrated in Table 4:

**Table 4. Funding and Repayment Terms**

Scenario (in no particular order)	Upfront Investment (Mortgage amount)	Term (years)	Assumed Interest Rate	Annual Payment made by City	Assumed Interest Rate	Annual Payment made by City
#1	\$2,000,000	15	7%	\$214,379.90	5%	\$189,790.40
#2	\$2,000,000	10	7%	\$277,425.60	5%	\$254,557.20
#3	\$1,000,000	15	7%	\$107,189.90	5%	\$ 94,895.28
#4	\$1,000,000	10	7%	\$138,712.80	5%	\$127,278.60
#5	\$3,000,000	15	7%	\$323,578.20	5%	\$284,685.70

Once the major infrastructure is purchased the majority of the costs of this program will relate to personnel, program development and building/operating costs. The cost to develop programs may be assumed by centres such as public health, NOSM or individual researchers in conjunction with band elders and members of individual reserves and/or communities.

**Risk and Critical Success Factors**

- Critical to the success of such an initiative is to ensure that all community members are aligned before proceeding. A strong desire to participate in such an initiative must exist at all levels of government (Federal, Provincial and within the cities), NOSM, various funding agencies as well as local businesses.
- The ability to design programs (research and teaching) that all stakeholders can participate in is critical to the success. These programs must be clearly identified and developed, and pilot projects undertaken and assessed. All stakeholders must feel a tangible reward is gained by partaking in the interaction.
- The potential acquisition of infrastructure for this project does pose some risk. If the program is not successful or not widely adopted then the ongoing expenses of the building must be serviced. Thus

the long term viability of a project must be assured. Hence significant dialogue and all-party buy-in is required before a business plan is developed.

- There is considerable interest to move a plan like this forward but care must be taken to ensure that all parties are aligned with reasonably expected outcomes, roles and responsibilities.

### Steps to Move Forward

**Figure 13. First Nations Health Research Network Timeline**

First Nations Health Research Network	Year 1 Q1	Year 1 Q2	Year 1 Q3	Year 1 Q4	Year 2	Year 3	Year 4	Year 5
<b>Step 1: Building the framework</b>								
Assess stakeholders participation								
Design governance and refine requirements								
Create framework for future discussions								
Conduct needs analysis								
Create pilot project								
Approach stakeholders and funding partners								
<b>Step 2: Implementation</b>								
Acquire appropriate infrastructure to carry out pilot project								
Develop follow on community based research and teaching projects								

## 4. Ethics Review Boards – Agreed Standards & Mutual Recognition

*Mid-term initiative*

### Summary

Ethics review boards perform an extremely important function by ensuring that clinical research is ethically acceptable, thus allowing better treatment and care of patients without harming or abusing them. When conducting clinical research, accessing sufficient numbers of patients often requires research to take place at multiple centres and hospitals. This results in a lot of duplicated process with the same project having to pass through multiple review boards.

The concept of this initiative is to have agreed standards across the region that would pave the way for mutual recognition of decisions while still allowing particular sites to do a local verification of ethics approval. This will allow multiple sites to give approve a project through a single application process. This will create a competitive advantage for the region to make it more attractive to do research there.

This is a key enabler of the collaborative and multi-centre nature of the proposed disbursed, networked research grid.

### Vision

This initiative will bring together the institutional ethics review boards of the hospitals and universities in the region to create a working committee to agree on a common set of standards and mutual recognition mechanisms.

### The Market Need

Harmonization of the regulatory environment is needed for effective utilization of resources and to make it easy for collaboration within the region and with other parties from beyond the region.

Collaboration was identified during the benchmarking work of this project as a key determinant of success, particularly for more remote benchmarked communities. Bringing partners together from other remote, but geographically-related, areas was very important for the benchmarked regions in developing critical mass, both in terms of developing a regional niche speciality, but also for attracting funding from external capital sources such as venture capital and attracting funding and industry partnering opportunities for research, clinical trials and commercialization activities.

For research that involves human subjects, collaboration within and beyond the region would be far easier if standardized guidelines are adopted with mutual recognition of the review boards within the region. This will allow a project that is approved in one centre to be carried out at several centres with fewer time delays and less administrative time and cost than is the case with multiple/repeated review processes which may or may not have the same objective and largely duplicate one another.

Lack of coordination of multi-centre clinical studies results in inefficient use of resources and capital.

Harmonization of the regulatory environment is needed to make it easy for collaboration within the region and with other parties from beyond the region.

Additionally, smaller hospitals, usually located in smaller centres, find it difficult to participate in research, because they lack the depth of in-house expertise to evaluate many of the research projects which would like to include some of their patients. During the course of this project, smaller hospitals have identified this as a barrier to their participation in research. Enthusiasm was expressed to make use of the ethics review board approvals of larger hospitals in the region.

## Background

### Objectives

Establish a working committee of institutional ethics review board.

1. Establish a working committee, most likely led by the institutional ethics review boards of the two universities and the larger hospitals that are going to be teaching hospitals for the Northern Ontario School of Medicine in Sudbury, Thunder Bay and Sault Ste Marie, but with as much participation as possible from review boards of smaller hospitals in the region.
2. Each review board will need to document its current guidelines to look for commonality. Most guidelines are likely to be already in existence as material supplied to new members that join the board. Where these don't exist, they will need to be formalized.
3. A task group within the committee will look for areas of common practice that already exist, which will need either little or no further discussion.
4. The areas of widely differing practice will have to be listed and worked through until an agreed standard is reached for each.
5. Once agreed standards exist, these can be formally adopted by all review boards in the region.
6. The mechanisms for mutual agreement will need to be developed. These may take the form of :
  - Institutions choosing to accept automatically the outcome of review boards of others. This is most likely in the case of smaller hospitals or centres with more generalist knowledge choosing to leverage the skills of larger ones with a greater depth of specialist knowledge.
  - Institutions still undertaking review if they have legal requirements for local review with which they must comply, but using a standard format for submission, which applicants need only prepare once, with one detailed review as a precedent, followed by multi-centre review.
7. Ongoing periodic review to update best-practice within the regional community of institutional review boards and as a forum to resolve any differences in the future.

The medical school is well-placed to act as a catalyst to get this process started.

### Strategy

#### Roles and responsibilities

Medical School: To act as a catalyst to get this process started, by raising awareness of need, using this report and by initiating fund-raising for the first piece of work to get an external group to facilitate the first few meetings and develop the work plan.

The primary people needed for this endeavor will be drawn from current members of existing institutional review boards.

Current review boards: To appoint people to the committee to carry out the process.

Researchers: To provide input to the committee on their experiences of applying for review and approval.

Project manager and administrative support: To co-ordinate the work and drive it forward in accordance with the work plan, collate documentation and minutes, travel, schedule and co-ordinate meetings etc.

Professional advisers: To act as a neutral facilitative third party in the initial stages for formation of the committee and developing the detailed work plan.

#### Human resources

The people needed for this endeavor will be drawn from current members of existing institutional review boards. These would be senior clinicians, scientists, academics or other knowledgeable parties who currently serve on a review board.

At minimum, one person would be nominated from each of:

- the review boards from the two universities,
- the medical school (though one person may represent the medical school and a university) and
- the regional hospitals/large health centres in the five larger centres.

Thus the core committee is likely to consist of 7-10 people. With participation from other centres, and “guest appearances” by researchers to give input, the total committee would be potentially 15 to 20 people in size. At least one of the members nominated would ideally have a legal background to ensure compliance of procedures developed with legal requirements for institutional review.

The universities and hospitals in Thunder Bay and Sudbury may wish to nominate 2 people, if the size and activity of the review boards justifies this approach.

The work of the committee will require a coordinating hub with a part-time project manager

In addition, there would be a project manager, part-time, with a part-time person giving administrative support, based in the region. This team would co-ordinate the work plan, arrange meetings, travel, videoconferencing, minutes of meetings etc.

One to two key members would be nominated from each of the larger ones at the Universities and larger clinical centres, e.g. this may be the chairperson or a suitable nominee to correlate and convey the input from a particular review board.

#### Processes and communications

The work of the committee will definitely require a coordinating hub, where the project manager will be located. Precisely where to locate this function would have to be defined by the project committee.

All members of the committee would have their own copies of the work plan and the project manager would be in charge of which members have which tasks to progress between committee meetings.

The convening of meetings should make as much use as possible of technology to minimize travel time and expense. The videoconferencing capabilities of the two medical school campuses at Sudbury and Thunder Bay can be used. For convening smaller meetings of task teams within the committee, teleconferencing could be used. For the larger, full committee meetings, in which there is likely to be a degree of sensitive communication and negotiation, it would be advisable to gather all participants in Sudbury and Thunder Bay so that they are all together either physically or via good quality videoconferencing in order to facilitate progress and avoid misunderstandings and inefficiencies.

#### Reward system

Ideally, there should be some form of bonus payment possible to members of the committee at points where they have reached the 3 to 4 major milestones of this undertaking.

However, contractually this may not be possible for many of the people who would be participating in work of this nature.

Other personal reward approaches can be taken such as 2-4 retreats for the committee at strategic points in the process at a congenial venue, which would allow for recreation as well as for informal discussion, idea sharing and team formation as people get to know one another better.

The overall reward for the institutions is greater attraction of research to the region, which attracts funding, upgrades to facilities, stimulation for its participants and growth of institutions in terms of their knowledge base and potential industrial partnerships.

## Regional Assets

The current stakeholders are the institutional review boards in the region and researchers or research groups, identified by those boards, which have brought a number of applications to a particular board.

The Review Boards should take the lead role to champion this collaboration, though the concept may have to be first introduced to the region by the medical school. In particular, the two universities and the larger clinical centre review boards will need to become key drivers, with representation from as many boards in the region as possible on the committee, with an appropriate number of those operating in the five largest centres in Northern Ontario.

The review boards would be the primary source of information and drivers of agreed approaches. However, they should use this process of developing agreed standards to get input from their clients, namely the researchers, including groups or companies, who submit projects through their processes. It will be important to “ask the customer,” in a sense, what in their experience

The overall reward for the institutions is greater attraction of research to the region, which attracts funding, upgrades facilities and is stimulating for its participants.

Review boards would be the primary source of information and drivers of agreed approaches.

leads to a streamlined process for both parties. This includes researchers and reviewers.

### Resources Needed

The primary people needed for this endeavor will be drawn from current members of existing institutional review boards. One to two key members would be nominated from each of the larger ones at the Universities and larger clinical centres, e.g. this may be the chairperson or a suitable nominee to correlate and convey the input from a particular review board.

To start the process, it would be advisable to have an outside party act as a neutral facilitator to conduct initial consultations, then set up and facilitate the initial meetings from which the committee would be formed and to assist with developing the program of work needed to develop agreed standards and mutual recognition mechanisms. Once the work program has been confirmed, the committee would continue with implementation.

A part-time project manager based in the region would be advisable to keep the initiative efficiently coordinated and to drive progress according to the work plan. This person may be identified within the current research administration at one of the two universities within Northern Ontario or possibly within NOSM itself.

Financial resources needed would include: funding for the initial work to consult with stakeholders, facilitate the first few meetings and develop the work plan - \$60,000-90,000.

This work would also determine more accurately the budget for conducting the full plan of work and implementing it. This would be of the order of magnitude of \$300,000 – 500,000 over a five year period. Most of this projected amount (~65%) is likely to be spent in the first 2 years in having appropriate standards and processes developed, implemented and adopted. The remainder would be spent over the next 3 years on ongoing review, updating best-practices and resolution of differences.

Principle drivers would include travel for meetings, outside professional advice such as legal counsel and part-time salary support to the institution hosting the project manager.

### Financial Strategy

Initial seed money to start off this budget should come from institutions that will participate in research and who fund an institutional ethics review board. Ultimately, this initiative will streamline the ethics review process, cut costs and free up people's time for other management, clinical and research duties by reducing the number of boards needed in Northern Ontario as well as the time spent getting projects approved.

An example of how greater efficiencies can be achieved was put in place some years ago when the separate ethics boards of the Sault Area Hospital and the Group Health Centre were replaced with a single board so that a research project could be rapidly and efficiently approved then carried out at both sites.

To start the process off, it would be advisable to get an outside party to act as a neutral facilitator and to request input from parties on streamlining the process.

This initiative will streamline the process, cut costs and free up management time.

The funding proportion that different institutions would ultimately contribute could be a percentage of their research budget, perhaps as a percentage of research overhead when applying for grants. Some of their contribution could be in kind (for example, people's time to a certain maximum – people in question would often be members of existing review boards).

For any ongoing costs of co-ordination and maintaining alignment from year 3 onwards, this could be in the form of a (modest) yearly fee from each participating institution.

Also, it would be worth approaching the local Northern offices of non-profit organizations such as the Alzheimer's and Stroke foundations to contribute to this initiative. Such contributions could be seen as significantly facilitating research in their areas in Northern Ontario. Currently some of these foundations raise as much as \$40,000 per year in Northern Ontario and end up having to export this money out of the region because they cannot find research initiatives on which to spend it within the region. These funds could be retained and partly spent on this kind of initiative.

If there is still a funding gap, FedNor or NOHFC could be approached to contribute to this as it would be a matched funding process.

Include a training program for those on ethics boards from smaller institutions and to bring in outside speakers to incorporate best practices. This would contribute knowledge to and enhance regional expertise which, in turn, will render the initiative more easily fundable.

Include a training program for those on ethics boards from smaller institutions.

### Steps to Move Forward

1. Conduct stakeholder consultations and facilitated sessions to network review boards and provide the foundation for the committee
2. Engage neutral external party to act as a facilitator
3. Form the committee
4. Define the detailed work plan
5. Apply for and raise funding
6. Committee initiates work plan
7. Develop common standards for ethics review
8. Develop processes for mutual recognition
9. Adopt and implement mutual recognition
10. Ongoing review, improvement and widening inclusion

### Critical Success Factors

Critical factors to ensure the success of this endeavour include:

- Participation by the majority of institutional review boards, and preferably all of those located at larger institutions
- The existence of a central point of co-ordination for the initiative (hence the need for a project manager, based in the region)
- Obtaining funding for the initial process to create the committee and work plan
- A genuine desire on the part of members involved on review boards to create a streamlined system to enable clinical research on as large a scale as possible, leading to a spirit of collaboration

A genuine desire to create a streamlined system to enable clinical research on as large a scale as possible will be critical.

- Input from researchers who have experience of putting in applications to review boards, preferably in more than one centre

**Risks**

Risks to the success of this initiative are principally failure of some or all of the above success factors:

- Insufficient participation by institutional review boards: no real interest develops in making this process as easy as possible for researchers, while still safeguarding patients’ interests
- Not appointing a project manager or having a similar point of co-ordination will mean there is no driving force measuring progress and reminding the participants of the next steps
- Failure to engage sufficient stakeholders
- No input from researchers who put in applications to review boards
- No desire on the part of members involved on review boards to create a streamlined system to be as enabling as possible for clinical research

**Milestones and Timelines**

**Figure 14. Ethics Review Board Timeline**

Ethics review boards – agreed standards & mutual recognition	Year 1-Q4	Year 2-Q1	Year 2-Q2	Year 2-Q3	Year 2-Q4	Year 3	Year 4	Year 5	Year 6
Engage neutral external facilitator	█								
Conduct facilitated sessions	█								
Form the committee		█							
Define the detailed work plan		█							
Apply for and raise funding			█						
Committee initiates work plan				█					
Develop common standards					█	█			
Develop mutual recognition processes						█			
Adopt and implement							█		
Ongoing review								█	█

## II. Basic Health Research Strategy

This is the second of three strategic plans proposed and consists of four initiatives, which are listed below. Each of these is then described in detail in this section.

1. Proteomics and Genomics Grid
2. Bio-prospecting
3. Collaborative Interdisciplinary Research and Commercialization Fund
4. Research Chairs and Fellowships

### 1. Proteomics and Genomics Grid

*Short- to Mid-term initiative*

#### Summary

An internationally competitive genomics program could be created by harnessing the unique assets of Northern Ontario's research and aspects disease pathology. Specifically, a unique genomics centre could be created by bringing together both nuclear and mitochondrial DNA research. By working through organizations such as the Public Populations Project in Genomics (P3G), this centre would focus on standardization within the genomics arena and should enable Northern Ontario to engage in globally competitive research. A diverse set of regional assets can contribute to building a viable and strong genomics grid. For example, genomics researchers, doctors and local community members could all participate by examining, collecting and donating tissue samples respectively. Even with a limited amount of funds, the genomics initiative can enter the global arena within one year by joining P3G. Once this international validation occurs, a wide variety of potential funding sources would be more supportive in such an initiative and many different projects could be supported.

#### Vision

The genomic/proteomic initiative's aim is to bring together the diverse assets of Northern Ontario to create a platform from which to build globally competitive research and development capacity while addressing the health needs of the local community. This platform would conform to international standards enabling global research collaborations to flourish. With an international focus, this initiative would not only adhere to but aid in shaping international genomic standards.

From an internationally recognized genomic or genomic/proteomic platform, specific projects would be rapidly developed. These projects would harness the unique assets in Northern Ontario to investigate and address the needs of the region with the goal of expanding these initiatives internationally. These needs would include better assessment and treatment of:

- *diseases* – identification of novel pathology e.g. diabetes and cancer
- *disease prevention* – identification of biomarkers or genes that identify disease susceptibility for exposure to environmental conditions

An internationally competitive genomics program could be created by harnessing the unique assets of Northern Ontario's research aspects and disease pathology.

- *diagnostics* – creating of new diagnostic tools and delivery techniques for better health care delivery to remote locations
- *improved treatment regimes*- identification of customized treatments using current or new therapies based on the genetic makeup of either the individual or tumor. This is a rapidly expanding and competitive field called pharmacogenomics
- *therapy discovery* – targets for rational drug design or assays for compound development could be designed from a genomics database.

Bringing together both nuclear and mitochondrial DNA research would create a unique genomics centre.

## Mission

The genomic/proteomic initiative enables the strong scientific acumen demonstrated with both nuclear and mitochondrial DNA research in Northern Ontario to act as a strong lever with which to capitalize on the unique assets and current research programs in Northern Ontario.

## Introduction

The examination of genes and proteins at the whole cell or organism level is termed genomics and proteomics respectively. Research centres throughout the world are undertaking genomic/proteomic type initiatives for a variety of reasons including falling startup costs, new areas of research for publication and the commercialization potential from scientific discovery. Even though centres may work in consortiums, there is a lack of standardization that is often required in order to create successful global partnerships. Some centres are beginning to realize this and are modifying or creating protocols that increase the likelihood of partnerships across industry, academic, non-profits and government sectors. When these initiatives are globally relevant they will succeed at attracting funding from international groups such as pharmaceutical and biotechnology companies, academic centers of excellence and large non-profit entities.

Northern Ontario's diverse set of resources are applicable to the genomic/proteomic field. Many of these resources are spread across multiple centres in different cities. Although this distance is normally viewed as a weakness in a traditional SWOT analysis, it can be viewed as an opportunity to create a strong competitive genomic environment. This distance requires a concerted effort to overcome these challenges through a consortium that minimizes duplication, shares resources through effective infrastructure use and has mechanisms to disseminate knowledge broadly. Recognizing that the Northern Ontario Biotech Initiative (NOBI) has already highlighted a mtDNA initiative, the proposal here is to expand this project into health research for Northern Ontario with globally significant results.

## The Market Need

The genomic market continues to expand from a variety of different forces. These drivers include:

- **Regulatory.** Agencies such as the FDA/TPD recognize that large blockbuster therapeutics may carry different adverse drug reactions depending on an individual's genome. For example, the class of cardiovascular lowering drugs called "statins" is recognized to pose health concerns in people with specific genes. Agencies are also

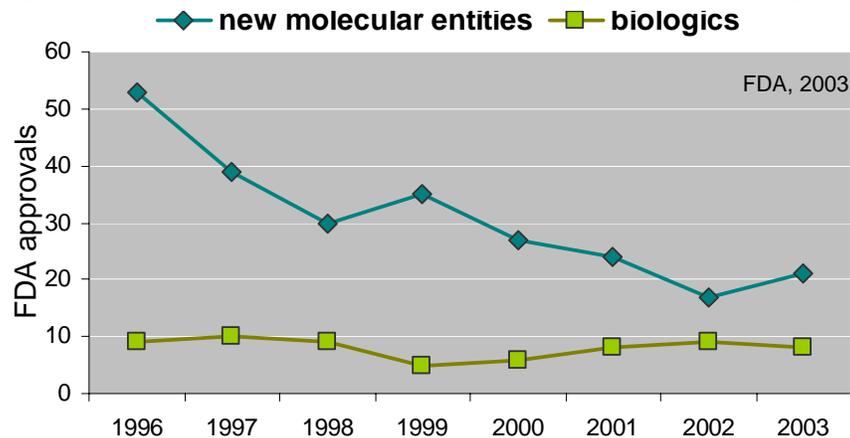
Market forces for genomics are creating an immediate demand for genomic data, analysis and research capabilities.

The drug pipeline over the past eight years has been decreasing.

recognizing that drug discovery and clinical trials are occurring with genomic data. Therefore the FDA in particular is stewarding in new regulatory guidelines for pharmacogenomic data submission policies<sup>7</sup>.

- **Drug discovery.** The drug pipeline over the past eight years has been decreasing. Pharmaceutical and biotechnology companies are addressing this by finding new therapeutic target through genomics and proteomics.

Figure 15. FDA Approvals for New Molecular Entities and Biologics



- **Diagnostics.** A demand exists for non-invasive diagnostics for disease indications and progression. With the advent of pharmacogenomics and new treatment regimes the early diagnosis will become increasingly important. However many of these tests are not *high margin* products but are based on volume pricing as automation becomes more common. Within Canada there are over 50 genomics-based companies and 10 genomic-based equipment makers<sup>8</sup>. Over half of these companies are in Quebec.

A number of companies have capitalized on the genomics market through a variety of mechanisms.

A number of companies exist that have built business around genomics and drug discovery. Example genomics companies include:

- **Small sized public company: Chondrogene** (Toronto, ON) is a genomics company with a research program to develop novel blood diagnostic tests. By collecting human tissue samples from various stages of a disease progression they were able to identify targets for novel therapeutics and diagnostics for diseases such as cancer. Chondrogene is a public company with a market capitalization of CDN\$38M.
- **Medium sized private company: Xenon Pharmaceuticals** (Vancouver BC) is a genetics-based drug discovery company. With research programs in neurology, obesity, cholesterol and iron they have raised over US\$80M since 1999. They have established

<sup>7</sup> <http://www.fda.gov/cder/guidance/6400fnl.htm>

<sup>8</sup> For a partial list see <http://www.genomequebec.com/asp/dirGenomicBref/industrie.asp?l=e>

partnerships with Pfizer and Novartis for cholesterol and obesity respectively and are actively looking for in-licensing products derived from genetic research. Xenon has actively searched for drug targets using genetic information from specific populations within Quebec.

- Large sized public company: **deCODE Genetics** (Reykjavik, Iceland) is a genetics-based drug discovery company that is granted exclusive rights to the genomic profile of the Iceland's population (~300,000 people) and was able to develop compounds for CVD, neurology, and asthma. With 7 compounds in their pipeline they have a market capitalization of US\$500M. With their subsidiaries, deCODE chemistry, deCODE biostructures and Encode Genetics, they also provide genomic, contract and clinical research services for pharmaceutical and biotechnology companies.

The rapid advances in biochemistry and molecular biology over the past twenty years led to a major genetic milestone of sequencing the human genome.

## Background

The rapid advances in biochemistry and molecular biology over the past twenty years led to a major genetic milestone of sequencing the human genome. This project, with both commercial and academic competitive participation, served to provide a foundation for research communities through the world to capitalize upon. With this framework, researchers are working with smaller populations throughout the world to identify alterations within a person's genetic code that would affect the probability of the expression of disease or specific trait within an individual.

Research focusing on the genome has been termed genomics, with this term applying to the exploration of genes, such as gene expression, interaction and potentially their products. Similar types of genomic/proteomic research are being conducted in other fields such as proteins (proteomics) and lipids (lipidomics). This research can further:

- greater understanding of disease susceptibility
- knowledge of the underlying mechanism of disease
- advances in genetic testing for disease screening
- identification in potential therapeutic targets
- greater understanding of therapeutic mechanism of action in a field termed pharmacogenomics

Commoditization of genomics research is beginning to occur within the global research community.

As with any new field, the competition rapidly changes with technological advances. During the initial stages of an emerging field, the greatest factors that limit participation within a given research community are mainly technological. By overcoming this initial barrier, innovation shifts towards commoditization or quickly lowering per unit cost. For example, The Human Genome Project spent over US\$3B in public funds to completely sequence the human genome from 1990-2003. The majority of this money was directed towards developing new equipment and only US\$300M was spent directly on sequencing<sup>9</sup>. With today's recent advances the current projected cost of sequencing a human genome with technology discovered in August 2005 is approximately US\$2.2M<sup>10,11,12</sup>. This rapid decrease in costs has

<sup>9</sup> [http://www.separationsnow.com/basehtml/SepH/1,1353,6-1-1-0-0-news\\_detail-0-2129,00.html](http://www.separationsnow.com/basehtml/SepH/1,1353,6-1-1-0-0-news_detail-0-2129,00.html)

<sup>10</sup> Bio-IT World. Harvard Group Develops Low-Cost DNA Sequencing Technique. August 05, 2005.

made genomics very accessible and, as such, allowed numerous research centres around the world to participate in a myriad of genomics research projects.

Standardization in genomics today should enable global competitiveness tomorrow.

The rapid rise of global genomic/proteomic based research, development and commercialization has created new opportunities and areas of research in almost every field of life science research and many fields of health diagnostics and delivery. This rapid rise in research and development interested has led to a lack of standardization within the –omic field. Currently the lack of standardization has not been a barrier to success within academic institutions. However, academic groups, national consortiums or individual researchers not standardizing their procedures on an international scale will create difficulties for global collaborations and thus marginalize research groups that create their own approaches. For example, there are many issues surrounding the collection of tissue samples for population based research. Many of these issues include:

- |                         |   |
|-------------------------|---|
| <b>Ethics</b>           | Each research institution, province or government may have conflicting ethical standards that may prevent global collaborations   |
| <b>Genetic material</b> | The type of material collected and stored is critical to conducting genetic research that is relevant to the international research community.  |
| <b>Data collection</b>  | Many types of information can be collected along with the genetic samples. This information may include such information as patient history and/or relevant diagnostic tests. Determining what information may be required (or useful) for international collaborations but within national or international ethical guidelines is critical for long term value for any genomics project. |
| <b>Analysis</b>         | The tools and techniques for genetic analysis continue to evolve and be refined. Results from tools such as gene chips and their associated analysis algorithms are difficult to compare between centres and chip makers.   |

Many of these issues arise when research groups act independently over large distances. This is the case for genomic researchers working in Northern Ontario, as highlighted with the NOBI Report<sup>13</sup>, which identified an opportunity to bring mitochondrial (mt) DNA researchers together under the banner of *Genomics North*. NOBI identified the opportunity to unify the research groups under the strength in mtDNA and suggested the creation of a MitoNorth database as a platform to build on. With the creation of Genesis Genomics, Molecular World and Paleo DNA, many companies are leverage Lakehead University's mtDNA expertise. Lakehead has been able to

<sup>11</sup> Shendure et al., Accurate Multiplex Polony Sequencing of an Evolved Bacterial Genome, Science 2005

<sup>12</sup> Collins, FS. 1999, NEJM. 341(1) 28-37

<sup>13</sup> The Northern Ontario Biotechnology Initiative. Submission to the Biotechnology Cluster Innovation Program. July 21, 2004. Prepared by SHI Consulting.

demonstrate that creating a genomic platform can bring jobs and capital into the region.

Here the opportunity exists to learn from this example and continue to build on this theme while expanding to include nuclear DNA and health research. Researchers within northern Ontario will better be able to compete internationally and attract external funding from both private and public sources by focusing on unifying northeastern and northwestern Ontario in the genomic/proteomics field under one platform that has international recognition.

## Background

### Objectives

The overall objective is to build a platform of genomics-based research that attracts highly qualified personnel and international funding to Northern Ontario. To achieve these goals this platform should be build with the following overall objectives:

#### *Northern Ontario*

- To improve the health of Northern Ontario populations
- Stimulate participation from all groups in medical research for local issues
- Develop a challenging environment that attracts and retains highly qualified personnel
- Creation of partnerships with other potential initiatives<sup>14</sup> to aid in building a health sciences research cluster
- Creation of new genomic-based firms

#### *Organization*

- Creation of an organization that encompasses both mtDNA and nuclear DNA groups and allows for academic or commercial collaborations
- Promote strong ties with research groups and communities within Northern Ontario
- Ensure that collaborations and genomic/proteomic research are internationally competitive
- Promote national and international collaborations with centres of academic and commercial excellence

#### *Standards*

- Adherence and/or participation in guiding emerging standards for academic genomic research
- Strive towards actively participating in developing international standards for sample collection, analysis and ethical considerations
- Ensure that the underlying infrastructure and standard operating procedures are designed and built to scale up with industrial-type efficiencies

Northern Ontario could build a genomics platform to shape and comply with international standards.

The genomics platform could establish both commercial and non-profit entities.

<sup>14</sup> Bio-prospecting, ethics review boards, community based clinical research institute, P3G partnership, etc.

#### *Genomic/Proteomic Identification*

- Assessment of key population groups within Northern Ontario (e.g. stable communities of >1000 people with limited or no migration)
- Identification of disease prevalence within specific isolated communities (communities with high disease prevalence such as diabetes or specific cancers)
- Identification of the willingness of specific populations, within a community, to participate in genomic/proteomic research
- Identification of potential research partners outside of Northern Ontario (academic, commercial and non-profit organizations in such places as Quebec, the United States and Europe) to collaborate research groups

#### *Collection, Storage and Analysis*

- Provide the methodologies and infrastructure to properly collect, store and track genetic material over a dispersed network
- Determine Northern Ontario/Canadian ethics guidelines for sample collection, storage, tracking and use
- Expand and build the infrastructure to analyze genomic, mitochondrial and proteomic data from samples collected for a variety of diseases (i.e.. cancer and cardiovascular disease)

#### *Application*

- Identification of specific research projects in the short, medium and long term that would work with this genomics initiative
- Selection of the highest priority project and ensure a “first win” to gain support for the broader application of the platform

#### *Sustainability*

- Development of the necessary infrastructure and associated personnel that is not wholly dependent on public sources of funds or a few contracts but is supported through diverse funding sources to ensure long term viability

### **Strategy**

Genomic/proteomic research is currently underway in Northern Ontario in such diverse areas as cancer, sepsis and paleontology. Primarily researchers in Thunder Bay are focused on mtDNA; whereas, Sudbury researchers are focused on nuclear genomic/proteomic type research within the cell excluding mtDNA. While this diversity is perceived to limit the formation of the critical mass required to build an internationally competitive environment for genomic/proteomic research, it can enable researchers from different research groups to unite while minimizing competitive nature between Northeastern and Northwestern Ontario. To accomplish this, the following steps should be considered to minimize risk and increase the chance of long term success:

Bridging the diverse research groups from mtDNA to sepsis and CVD will enable critical mass to quickly form.

### Structure of the genomic/proteomics grid

A non-profit governing body should be created. This body would act as the umbrella organization for the genomic/proteomic initiatives in Northern Ontario. This would act as an interface for collaborations, funding and policies on a national and international scale. The advantages of such an organization would be:

- Creation of a large platform from which to interact with large groups such as the Estonian Genome Project<sup>15</sup> or the Centre for Integrated and Genomic Medical Research<sup>16</sup>
- Development of a unified access point for private companies to interact with genomic researchers and determine intellectual property issues
- Ability to apply for larger funding initiatives
- Increased ease of smaller communities to participate in research (e.g. sample collection) and work with larger institutions

### Roles and responsibilities

Key personnel would be required for such an initiative:

- **Scientific Director (Consortium Leader)** that would provide critical leadership and aid in unifying the participating research groups and cities; monitor progress and ensure financial stability while identifying new national and international opportunities. The position will also ensure that the needs of both the nuclear and mt genomics research projects are being met through resources and information exchange.
- **Research Director, mtDNA genomics.** Researcher to coordinate the efforts of the mtDNA genomics group and liaise with the nuclear and scientific directors.
- **Research Director, nuclear genomics.** Researcher to coordinate the efforts of the nuclear genomics group and liaise with the mtDNA and scientific directors.
- **Project partners (remote communities, other genomic centres, industry and public health).** The project partners are those stakeholders who bring their expertise, know-how, and resources to the consortium. Each region and resource involved in this initiative should be represented. As member of the consortium they are involved in decision making, are co-applicants to grant applications, and participate to intellectual property ownership.

<sup>15</sup> <http://www.geenivaramu.ee/>

<sup>16</sup> <http://www.postgenomeconsortium.com/cigmr/index.html>

Whole communities can participate in this initiative, from genomics researchers to community members donating tissue samples.

### Human resources

The needs for human resources will be determined based on the final research plan in both this report and the mtDNA initiative (NOBI report) the scope of the initiative, the number of partners engaged in the project, and the timelines set forth. The human resource needs should include the following categories:

- genomic/proteomic researcher
- Technicians
- Students
- Administrative support
- Community support personnel

### Infrastructures, equipments, tools & systems

The infrastructure required to undertake such a project is varied and complex. The first step in the process is to quickly determine the long range goals of both the mtDNA and nuclear DNA groups. The required infrastructure exists on a small scale to undertake smaller pilot project in individual centres. Each group is likely evaluating, planning and undertaking major equipment purchases. By coordinating efforts, selection of equipment and infrastructure requirements in the near term will aid in facilitating the unification of these groups and reduce the need for specific equipment purchases. Specifically the requirements for specialized databases, banks and analysis are under potential evaluation and the opportunity exists to ensure to acquisition of equipment that can scale for Northern Ontario populations and beyond.

### Intellectual property

The ability to commercialize or protect discoveries is a key concern for a various groups. If a commercialization strategy exists, this may prevent specific collaborations with international organization such as the Public Population Project in Genomics (P3G) Consortium<sup>17</sup>. Conversely the ability to commercialize and develop new discoveries aids in creating sustainable business models. Thus a model similar to the Consortium for Post-Genome Science<sup>18</sup> could serve as an attractive option. In this model there is a governing organization that allows for commercialization with a subgroup that is specifically organized for the public dissemination of information and for academic and non-profit collaborations.

## **Commercialization**

Attracting venture capital to Northern Ontario with the purpose of commercializing life science ventures have proven difficult. Primarily this is a result of:

- *External environment* – The Canadian VC market prefers to invest in major centers such as Toronto, Montreal and Vancouver since these clusters have a track record with appropriate highly qualified people and large supporting infrastructures.

<sup>17</sup> <http://www.p3gconsortium.org>

<sup>18</sup> <http://www.postgenomeconsortium.com>

Commercialization models currently exist for successful genomics companies.

- *Internal environment* – Northern Ontario has not traditionally had the life science spin out opportunities due to the small number of research groups, lack highly qualified people (scientific and management) and large distances to cover in order to work together.

To overcome some of these issues, the ideal profile of a company would be one that has a service and a research division. The service division (akin to a diagnostic arm) would identify needs within Northern Ontario and solve a local problem. The revenue generated from the service division would aim to offset the requirement for multiple rounds of VC funding. This model would also be used to within the non-profit subsidiary where diagnostic revenue would offset operating costs. Examples of these services in Northern Ontario include:

*Molecular World* (Thunder Bay, On)<sup>19</sup> is a mtDNA biotechnology company with a diagnostic arm. This company has developed competitive testing services that include:

- Paternity
- Forensic
- Ethnicity
- Relationship
- Genetic disease testing

These services are nationally accredited ensuring a standard of quality control while bringing in revenue to support research and development efforts that solve Northern Ontario problems but with a global market. For example, blood tests are being developed that would reduce the need for complex procedures, such as amniocentesis, that are difficult to deliver in remote communities since highly qualified personnel are required to perform the test. This directly would benefit the lives of Northern Ontarians living in remote communities but would also have a far greater impact to prenatal healthcare delivery.

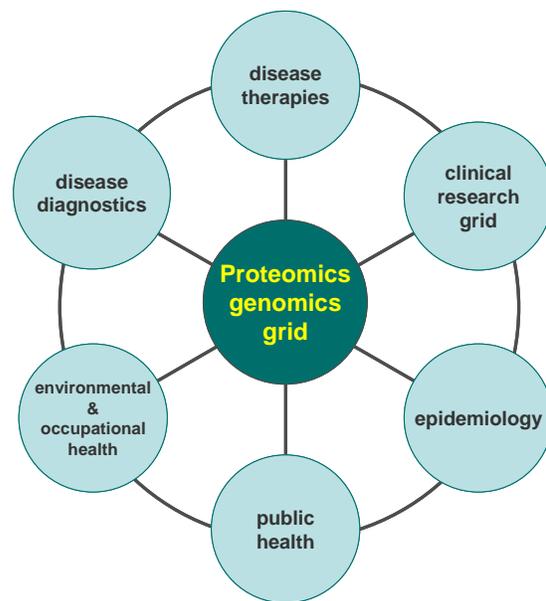


Figure 16. Proteomics and Genomics Grid

The genomics platform can support, and act in concert with, other initiatives to create critical mass.

*Genesis* (Thunder Bay, On)<sup>20</sup>, another mtDNA biotechnology company has created a skin diagnostic test for the early detection of cancer. This diagnostic is currently for sale in the United Kingdom. This international approval is critical towards gaining national exposure.

<sup>19</sup> <http://www.molecularworldinc.com>

<sup>20</sup> <http://www.genesisgenomics.com>

*Paleo-DNA* (Thunder Bay, On)<sup>21</sup> specializes in analyzing degraded or low copy number DNA samples. This company offers forensic, paternity, sibling relationship, archaeological and training services for nuclear, pathogenic and mt DNA analysis.

### *Expansion*

The genomic/proteomic platform is one that would support other projects that are occurring or need to occur within Northern Ontario. With the proteomic grid at the center, multiple smaller projects could be leveraged using this platform. These include:

- epidemiology - with any successful genomics initiative a strong component is required to understand and characterize disease prevalence within a community
- clinical research – strong ties with community based medicine would assist in sample collection and disease identification
- public health – this department can bring together disease identification and prevention and prevention strategies using novel genomic testing
- environmental and occupational health – current initiatives with non-life science companies (e.g. mining) could be expanded to changes in disease pathology and prevalence after exposure to specific environmental conditions with specific reference to a specific genotype
- disease therapies – using specific genetic information further insights into the creation of new therapies or use of current therapies can be examined
- disease diagnostics – with the collection of genomic information from specific disease populations, certain genetic and bio markers could be identified for specific diseases

## **Regional Assets**

There are numerous regional assets that can serve to move this initiative forward. These include:

### Scientific and genomic

- Nuclear genomic researchers and associated genomic equipment at
  - Sudbury's Northeastern Ontario Regional Cancer Center
  - Thunder Bay's Northwestern Ontario Regional Cancer Care Centre
- Clinical research assets at NEUREKA!
- mtDNA research at Genesis Genomics, Molecular World and Paleo-DNA
- Bioinformatics software from Cormac Technologies
- Patient database of 58,000 medical records, at the Group Health Centre in Sault Ste. Marie.
- ORION telecommunications network for rapid data transfer
- Specialized well-characterized tumour cell lines
- PhD program at Laurentian University in Molecular Biology
- ICR discoveries in Thunder Bay
- Lake Superior Centre for Regenerative Medicine

A diverse set of regional assets can contribute to building a viable and strong genomics grid.

<sup>21</sup> <http://www.ancientdna.com/>

- Algoma CHFNet Cardiogene Study
- Group Health Centre's 42 years of paper archives for cancer
- Capability for electronic archiving of paper records – St. Mary's Historical Database
- Autologous blood donation - \$1.5M machine now idle with full trained staff available in Ste. Saint Marie
- Forensics lab in Ste. Saint Marie – Centre for Forensic Sciences (Northern regional)
- ULERN – linking environmental and human health
- Call centres - both in and out bound
- Aging demographics that is associate with a high incidence of
  - cancer
  - cardiovascular disease
  - renal disease
- Remote or isolated communities with
  - high incidence of diabetes (reportedly up to 88% in some communities)
  - populations of 400 people with very limited population migration
- NOSM faculty members in epidemiology, biochemistry and molecular genetics
- Proteomic and genomic equipment at both Laurentian and Thunder Bay university and hospital research centres

## Financial Strategy

### *0-12 months*

The first step in setting forth would be to identify participating research institutions. Within the first 6 months a small startup fund of \$30,000 should be created. These funds would be directed towards setting up an appropriate vehicle that would enable institutions and research groups to participate. The budget for such a fund would be: one third for the creation of an entity, one third for the membership to an international consortium and one third for travel and information gathering. This would also enable the group to join an international consortium, such as P3G, and travel to the meetings with 1-2 scientists. These meetings will enable the consortium determine such things as:

- approach
- framework for model
- competitive landscape

Key dates: September 19-20, 2005: P3G annual meeting in Hinxton (near Cambridge) England.

By joining an international organization and participating in with working groups while potential organization international collaborations (or at least letters of intent), the chances to successfully apply for funding should increase. The increase will in part be due to the international recognition but also the discussion that will center on brining researchers together across Northern Ontario in order to undertake such an initiative. Also by joining an international group, the genomics initiative could gain access to international funding grants that would be announced. Most likely, these grants would require international partnerships.

With a limited amount of funds, the genomics initiative can enter the global stage within one year.

A wide variety of potential funding sources could be accessed including government and NGOs.

The next funding step would entail a smaller research project that would require the participation of a variety of groups. One that is ideal for this engagement would be the *CIHR: Novel Population Genetic and Genetic Epidemiological Approaches for Studies of Complex Traits - Operating Grant*<sup>22</sup>. This grant is supported by *CIHR: Institute of Aboriginal and People's Health*<sup>23</sup>. This would fund equipment (first year) and research personnel for the length of the grant (3 years). The funds would total \$100,000 / year for three years.

Key dates include:

- December 1, 2005 Registration Deadline - Registration packages must be courier stamped by this date.
- January 16, 2006 Full application deadline - Full applications must be courier stamped by this date.
- April, 2006 Anticipated notification of decision and start date

The genomics committee would be required to identify projects that would create a first win. This small scale pilot project would be important to test many of the issues that would arise on a larger scale.

#### Years 1-3

By the end of the first year, an organization could be set up. Since researchers in Northern Ontario are working with biotechnology or pharmaceutical companies, it is likely that these companies would make investments into laboratories or groups in order to carry out the research or participate in clinical trials. It would be possible to leverage this funding from FedNor's Innovation and Capital Building projects. With 50% of the costs covered by industry the genomic/proteomic initiative could increase its required infrastructure in a cost effective manner.

The CFI New Initiative Funds aims at applications that have not been previously supported by the CFI with the goal of promoting world-class and innovative research beyond the means of Canadian institutions.

This initiative should also strongly consider a CFI New Initiative application. Since the genomic/proteomic proposal would be multidisciplinary and multi-institution while building research capacity and through the creation of platform that can be leverage in future initiatives. The CFI New Initiative Funds aims at applications that have not been previously supported by the CFI with the goal of promoting world-class and innovative research beyond the means of Canadian institutions. Here this initiative would be suitable since it would capitalize on research across the cities, build local and international networks and partnerships; while retaining and attracting researcher and ultimately create socioeconomic benefits for Northern Ontario and Canada.

Key dates include:

- November 15, 2005 Notices of Intent
- February 13, 2006 Strategic Research Plan Summary and Applications
- November 2006 Board Decisions

Note: CFI will fund 40% of eligible costs. Additional matching funds should be sought from:

<sup>22</sup> <http://www.cihr-irsc.gc.ca/e/28278.html>

<sup>23</sup> <http://www.cihr-irsc.gc.ca/e/26653.html#IAPH%20Other>

- International funding sources
- Industry – there are projects underway with mining companies to assess the markers for susceptibility for cancer. Industrial partnerships such as these should be investigated aside from large pharmaceutical or biotechnology companies. Other partnerships could include steel manufacturers in Ste. Saint Marie (workers have a higher incidence of bladder cancer). This was not investigated for this project.
- Non profit organizations such as the *Heart and Stroke Foundation*<sup>24</sup>. This foundation is interested in funding larger size research projects, development of multi-centre program/group grants for our researchers and grants that increased duration of funding. This type of funding would be ideal to investigate the genomics of specific disease indications. The genomics initiative would fit all of these criteria. Other non profit organizations should be investigated.

To create sustainable model, it will be important to develop a non profit service unit. This would likely involve diagnostic testing (akin to the mtDNA testing initiatives) or the creation drug screening technologies that are created using proteomic and genomic screens. This would aid in supporting the ongoing costs of discrete aspects of the research.

*The Ontario Research Fund (ORF)*<sup>25</sup> should be considered for ongoing support of this initiative once proof of concept type projects has been funded and have been successful. From these smaller projects, the operating costs and long term capital costs can be better determined. This fund can support both direct costs (salaries, facilities, management and administration) and indirect costs (overhead of research). This fund also will require a knowledge transfer or commercialization strategy for the genomic initiative.

*Genome Canada* has not announced another funding round. If there is an announcement then this project should be prepared to submit an application.

### Risk and Critical Success Factors

1. Northern Ontario does not have a large group of nationally and internationally competitive genomic/proteomic researchers. Critical to the success of this initiative will be the attraction of key people while fostering local researchers.
2. Ability to unite nuclear and mt DNA researchers under with one unified organization.
3. Ability of consortium members to obtain nationally and internationally competitive funds. To mitigate this risk, consortium members should propose to undergo an internal review process with other consortium members to increase chance of success.
4. Ensure the participation of stakeholders from numerous groups such as individual communities that will participate in providing genetic samples.
5. Creation of Northern Ontario/Canadian ethics, commercialization standards that will enable various communities, research groups and stakeholders to efficiently participate.

Leadership is required to unify diverse research groups across the region.

<sup>24</sup> <http://www.hsf.ca/research/>

<sup>25</sup> [http://www.ontario-canada.com/ontcan/en/rtts/rtts\\_orf\\_res\\_excellence.jsp](http://www.ontario-canada.com/ontcan/en/rtts/rtts_orf_res_excellence.jsp)

## Steps to Move Forward

The next step is to determine the level of serious support by all the stakeholders. This initiative is broken down into 4 steps to ensure that the build out of infrastructure and capacity is:

- warranted
- sustainable
- suited for the long term vision of the genomics platform

### Step 1: Create the consortium, Year 1

- Appointment for 1 year two group leaders: 1) nuclear and 2) mt DNA group (as outlined in NOBI)
- Identification of research groups willing to participate
- Write a proposal to participating research institutions to put in seed funding to initiate group
- Creation of a non-profit consortium
- Join international genomics group
- Inventory of current infrastructure
- Develop a long term vision that current genomics researchers can agree upon
- Creation and prioritization of a list of pilot-type projects that would act as a foundation for an individual project
- Identify key funding agency to apply towards the project
- Identify potential industrial partners (biotechnology, mining etc)

### Step 2: Undertaking a Pilot project, Years 1-2

- Identify research contracts (industrial) that could be relevant to the pilot genomics project
- Secure funding for initial pilot project from public and/or private sources
- Conduct research and begin to build out the genomics database
- Ensure results are published in high quality journals
- Identify and share lessons learned with team members
- Identify key personnel and funding sources for larger scale follow on project
- Identify international groups for partnership (e.g. members of P3G)
- Create strategic research partnership to enable access to international funding agency (e.g. European Union)

### Step 3: Scale up, Years 2-3

- Ensure pilot project was sustainable and the necessary infrastructure for scale up is identified
- Obtain industrial research contracts that can be leveraged with NSERC, CFI or ORF
- Apply for CIHR and/or international funding agency for operating and infrastructure grant leveraging knowledge and skills in pilot project
- Upon successful award undertake population genomic research
- Develop a business plan for a non-profit service arm for consortium
- Apply for seed funding from NSERC and/or FedNor for a non-profit service
- Create an commercialization strategy
- Identify 3 potential commercial opportunities and rank each one
- Develop business plan to commercialize one technology

Small pilot projects can demonstrate proof of concept before committing larger amounts of funds.

- Identify future partners (i.e. public health, CVD technology platform etc)

Step 4: Node expansion

- Develop plans to integrate future project into consortium (e.g. CVD project, oncology screening, working with the clinical research initiative or aboriginal health)
- Apply for funding from specific funding agencies (other than CIHR and NSERC) to expand grid (i.e. CVD project would apply to the heart and stroke foundation)
- Plan on expansion of modules as the scientific rationale is put forth

**Figure 17. Genomics Grid Timeline**

Genomics Grid	Year 1 Q1	Year 1 Q2	Year 1 Q3	Year 1 Q4	Year 2	Year 3	Year 4	Year 5
Step 1: Creation of the Consortium								
Step 2: Undertaking a pilot project								
Step 3: Scale up								
Step 4: Node expansion(s)								

## 2. Bio-prospecting

*Short- to Mid-term initiative*

### Summary

Bio-prospecting for pharmaceutical compounds is the search for economically valuable biological molecules, organisms, or genetic material from nature.

Bio-prospecting for pharmaceutical compounds is the search for economically valuable biological molecules, organisms, or genetic material from nature. Northern Ontario is a vast and diversified region rich with natural resources, which makes the region an excellent location for conducting bio-prospecting. In addition to aboriginal knowledge in natural medicine, the region is host to several academic research groups and networks that have developed expertise, technologies, and databases that could be leveraged in a bio-prospecting initiative.

The recent decrease in productivity in pharmaceutical discovery has promoted the search for new ways to discover drug leads. The bio-prospecting initiative aims at making Northern Ontario an internationally recognized centre for bio-prospecting. The consortium will provide leadership to bring multiple stakeholders into a multidisciplinary endeavor that will leverage one of the largest national 'libraries' of bio-products, e.g. the Canadian North.

Key infrastructure and equipment will include GPS based systems, web-enable data management systems, analytical laboratories, molecular and cellular biology laboratories, as well as teaching facilities. Communication will be channeled through a project manager that will coordinate the activities and communicate progress to the member with the aid of communication infrastructure such as video-conferencing. The bio-prospecting initiative will seek funding from federal agencies such as the NCE, CRC, and CFI as well as from local partners such as FedNor and NOHFC. Drug discovery is a risky endeavor, and multi-national pharmaceutical companies now recognize that diversification will be critical to scientific success as well as strategic partnerships with non-traditional partners.

### Vision

This vision is to become a leading centre for bio-prospecting.

The bio-prospecting initiative aims to bring together the wealth of expertise, know-how and infrastructures in Northern Ontario to leverage the unique assets of its natural resources, and to become an icon centre in bio-prospecting for new drug discovery.

### Mission

The bio-prospecting mission is to create the medical and scientific leadership that will set the bio-prospective strategy, and provide expertise and capability in sample collection, sample cataloging, bio-analytical tools, purification technologies, as well as in screening assays to investigate the natural resources of Northern Ontario for the identification of new medicines. The initiative will recruit key regional stakeholders and bring them into a cohesive team to identify and secure access to local natural resources, knowledge, and expertise.

## The Market Need

Bio-prospecting for pharmaceutical compounds has yet to become a crowded market. Until recently, the pharmaceutical industry was complacent with its traditional discovery paradigm revolving around chemical compound libraries. But lately, decreasing productivity in pharmaceutical discovery has forced industry to seek new ways to discover drug leads.

Nature is a fundamentally rich pool of complex molecules with bioactive properties, and the likelihood of finding bioactive molecules is certainly higher than in a library of randomly generated chemical entities. However, this resource has not been extensively leveraged due to a lack of analytical tools and screening assays. The latest decade has yielded a greater understanding of molecular biology and brought countless tools that now render bio-prospecting an efficient approach to drug discovery.

One of the greatest examples of the potential of bio-prospecting is the oncology drug Taxol that is extracted from the Yew tree. Taxol has been one of the most prescribed anti-neoplastic drugs of the last decade. Furthermore, several emerging health-focused biotechnology companies have built their research around bio-prospecting, to name a few:

- **CV technologies Inc.** (Edmonton, AB); is developing pharmaceutical preparations from nutraceuticals. It is using a proprietary technology to upgrade nutraceutical preparations to pharmaceutical standards.
- **Ecopia Inc.** (Montreal, QC); Ecopia's discovery activities are based on the identification of drug leads from bacteria known as the *Actinomyces*. These bacteria have previously provided drugs such as *Streptomycin*, *Erythromycin*, *Amphotericin*, and *Doxorubicin*.
- **Aeterna Zentaris** (Quebec, QC); Aeterna's antiangiogenic drug for cancer originates from shark cartilage.
- While many more examples exist, one was recently in the media (Reuters), where researchers in the United States and Australia are isolating powerful antibiotic from crocodile blood (Dr Mark Merchant and Dr Adam Britton).

## Background

### Objectives

- Create a consortium for bio-prospecting in Northern Ontario that would regroup the potential stakeholders in Northern Ontario
- Provide leadership for regional bio-prospecting
- Create a training program for field work in bio-processing, data management technologies, and laboratory work
- Provide research infrastructures for sample analysis and screening
- Provide high quality and high profile training in bio-prospecting for students and adults in continuing education
- Export expertise in bio-prospecting in other regions of the world and sub-contract sample cataloging and data-management
- Discover drug leads from:

The recent decrease in productivity in pharmaceutical discovery has forced the industry to seek new approaches to drug discovery.

The bio-prospecting consortium will provide leadership to bring the multiple stakeholders into a multidisciplinary endeavor that leverage one of the greatest regional wealth.

- Plants
- Medicinal plants known by Aboriginal people.
- Microbiologics (Micorrhizal fungi, others)
- Others (including water, soil, etc.)
- Commercialize discovered drug leads

### **Strategy**

The bio-prospecting initiative will be multidisciplinary and have multiple stakeholders. It first needs leadership to bring all participants together. It further needs to build management structures, acquire tools to carry on the research activities, recruit specialized personnel, and secure or build physical infrastructures. The strategy is thus defined by the creation and alignment of resources and structures that will actualize the objective of the initiative.

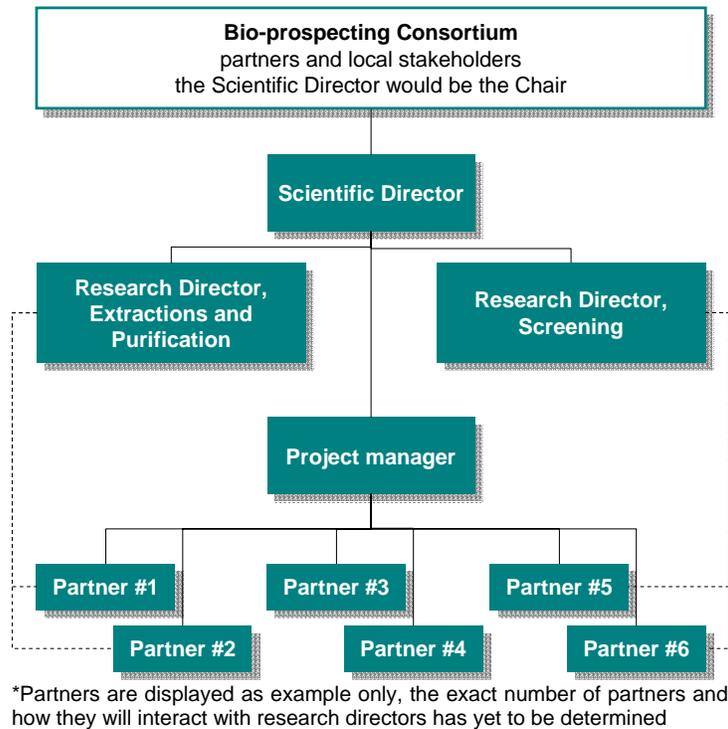
#### Roles and responsibilities

- **Scientific Director (Consortium Leader)**  
The Scientific Director will be responsible for providing leadership to this initiative and overseeing the scientific excellence of the project. He will have the mandate to bring cohesion among the partners, to monitor research progress, and to identify opportunities and threats.
- **Project Manager**  
The Project Manager is responsible for the daily coordination of the research activities, ascertaining efficient logistic between partners (those that collect samples, those that extract and purify molecules and those that test and screen them). The Project Manager is also responsible for coordinating the grant applications and communicating research progresses to the Scientific Director. The Project Manager will be further responsible for supporting commercialization implementation with the Scientific Director.
- **Research Director, Extractions and Purification**  
This director should be one of the partners involved in samples extraction and purification. This person will take a leadership role in overseeing the overall extraction and purification activities from the partners. This Director would be responsible for centralizing and communicating the collective know-how in extraction and purification, ensuring that procedures meet the needs of the partners involved in testing and screening, as well as being pro-active about aligning current methods with future scale up and GMP imperatives.
- **Research Director, Screening**  
This director should be one of the partners involved in drug screening that would take a leadership role in overseeing the overall screening activities from the partners, and will be responsible for centralizing and communicating the collective findings of bio-prospecting, and ensuring that promising hits are further investigated.

- **Project partners**

The project partners are the stakeholders who will bring their expertise, know-how, and resources to the consortium. Each region and resource involved in this initiative should be represented. As members of the consortium they are involved in decision making, in being co-applicants to grant applications, and in the participation of intellectual property ownership.

**Figure 18. Bio-prospecting Consortium**



Key infrastructure and equipment will include GPS- based systems, web-enable data management systems, analytical laboratories, molecular and cellular biology laboratories, as well as teaching facilities.

Human resources

The need for human resources in addition to the management team described above will be determined based on the final research plan, the scope of the initiative, the number of partners engaged in the project, as well as the timelines set forth. The recruitment of a dozen dedicated resources would represent a conservative starting figure. The human resource needs should include the following categories:

- Teachers/ Professors
- Research assistants
- Technicians
- Students
- Administrative support

Infrastructure, equipments, tools & systems

The initiative will require key infrastructure and equipment for sample cataloging; including GPS based systems, web-enable data management systems, analytical laboratories, molecular and cellular biology laboratories, as well as teaching facilities. Detailed

infrastructure and equipment needs will be determined following the creation of a detailed research plan, and will depend on:

- The identification of current infrastructures (partners' laboratories and equipments that can be leveraged in this initiative)
- The current capacity of the infrastructures
- The determination of new infrastructure and equipment needs

Communication will be channeled through the project manager that will coordinate the activities and communicate progress to the member with the aid of communication infrastructure such as video-conferencing

#### Processes and communications

Scientific and strategic decisions are the responsibility of the Consortium under the leadership of the Chair (Scientific Director). Research coordination and communication should be managed by the Project Manager. The Project Manager should be promptly informed of progresses and of any unexpected situations; concomitantly, the project manager has the responsibility to communicate to all partners, progresses and issues as required and on a regular basis. Non-disclosure and confidentiality policies need to be enforced by all partners to allow intellectual property protection of discoveries. The Project Manager should communicate progress with the Scientific Director on a weekly basis and the Consortium should meet quarterly to discuss project progress and future directions. Because of the distance separating the various partners in this dispersed business model, communication infrastructures such as tele-education, video-conferencing, web-enable databases and electronic forums or billboards would be required to empower this team to be efficient and effective.

#### Reward system

As this initiative will represent a side project for most partners, it is important that practices are put in place to keep the stakeholders engaged and motivated. This should be achieved through the three following incentives:

- Involvement in decision making
- Be regularly informed of progress
- Have intellectual property participation in consortium commercial outcomes

### **Regional Assets**

- The Northern College of Applied Arts and Technology in Timmins would be interested in creating a technical program to train Northern Ontario resident in bio-prospecting. The program would include basic biology, data collection, IT technologies, and laboratory basics. The program would also provide continuing education for workers from other industries that wish to develop new skills and redirect their career from declining sectors to the growing economy of biotechnology
- Researchers in the Geography department at Laurentian University are conducting research that is mapping epidemiological data from patients and clinics to determine where given health care services are most needed. Their expertise and technologies could be contributed to this initiative

- Thunder Bay would be interested in building a green house that might support the growth of plants that would be identified from this initiative.
- Aboriginal communities represent key assets for this initiative. Communities' members should be invited to participate in this initiative. While all community members would be welcomed to be trained and to participate in the several aspects of the initiative, the key leaders that own the knowledge in aboriginal medicine should be members of the consortium and be part of the decision making process.
- Laurentian University & Northeastern Ontario Regional Cancer Centre in Sudbury have developed unique cell lines to test a drug for chemo-resistant tumors. These cell lines could be provided for compound screening. Furthermore, laboratories at the North Western Ontario Cancer Centre, ICR Discovery, and researchers in both Lakehead and Laurentian Universities could come together as partners for sample processing, analysis, screening, and clinical development.
- Several organizations in Northern Ontario are potential partners in bringing natural resources (samples), resource expertise, biology expertise, chemistry, or molecular biology resources and expertise. Such organizations include the Great Lake Forestry Centre (Sault-Ste-Marie), Mikro-tek (Timmins) which has expertise in soil and Micorrhizal fungi, ULERN (Sault-Ste-Marie), and the Northern Ontario Plant Database (Sault-Ste-Marie)

### Infrastructure Gaps and Resource Needed

- The creation of a bio-prospecting consortium, despite its virtual structures, will require administrative resources.
- The program for training in bio-prospecting will require teaching space, educational material, and laboratory equipment.
- Research infrastructures to support sample collection activities, processing, storage, analysis, and screening.
- Professional resources for promotional and commercialization activities, including an interactive web-site.

### Financial Strategy

The Network of Centres of Excellence should be explored for the funding of the consortium. Alternatively, local funding may be solicited (local stakeholders, FedNOR, the Northern Ontario Heritage Fund Corporation). In absence of successful fund raising from these sources, the partners of the consortium could create a common fund from their internal budget, if these allow for discretionary spending. The NCE's mission is to support multi-sectoral programs that foster partnership between university, government, and industry. Among its goals it seeks to stimulate entrepreneurial talents in order to translate innovation into economic and social benefits for Canadians.

Given the importance of the bio-prospecting initiative for NOSM and the two universities, the universities should apply for a Canadian Research Chair to cover the salary of the Scientific Director. The Canada Research Chairs Program offers funding to universities to appoint outstanding researchers for senior professorships in areas that are aligned with the institutional strategic directions. It is the university that nominates researchers for a chair

The bio-prospecting initiative would seek funding from federal agencies such as the NCE, CRC, and CFI as well as from local partners such as FedNor and NOHFC.

application, and the nominees then submit essential personal application information. There are two types of chairs: Tier 1 Chairs, for outstanding researchers that are world leaders in their fields (\$200,000 annually for seven years), and Tier 2 Chairs, for exceptional emerging researchers (\$100,000 annually for five years). Chairs are for full-time appointments. The next nomination rounds are September 2005, and December 2005.

The initiative would be very competitive for infrastructure funding through a CFI new initiative application.

The initiative would be very competitive for infrastructure funding through a CFI new initiative application. This is an initiative that is multidisciplinary and multi-institution, and that builds research capacity and creates a platform that can be leveraged in future initiatives. NOSM can undoubtedly write a compelling application for CFI funding. The CFI New Initiative Funds aims at applications that have not been previously supported by the CFI and that promote world-class and innovative research beyond the means of Canadian institutions including initiatives that are linked to new ideas, to different and better ways of performing research, and that capitalize on excellent research, build networks and partnerships, as well as initiatives that attracts and retain the best researchers, generate socioeconomic benefits for Canada, and lead to improvements to society and quality of life. Applications will be due on February 13, 2006 and funding decisions rendered in the Fall of 2006 with the letter of intents also to be submitted this fall. As for previous rounds of funding, CFI will fund 40% of eligible costs. Furthermore, the new initiative funded initiative will be eligible for the infrastructure operating fund, and can potentially fund operation to up to 30% of the funding award. Additional matching funds should be sought through the Northern Ontario Heritage Fund Corporation, FedNOR, and/or private partners (financial support from companies that have a stake in the initiatives, and can come in the form of in-kind contributions).

Key dates:

- November 15, 2005 Notices of Intent
- February 13, 2006 Strategic Research Plan Summary and Applications
- November 2006 Board Decisions

Operating grants for discrete projects should be funded by the CIHR and/ or NSERC. The CIHR is the premier health research agency in Canada. It funds research in all areas of health science. Beside traditional research grants, it also provides team grants for large scale projects. NSERC also provides operational grants, fellowships, and scholarships for university-based research projects including health focused research. Programs of particular interest at the NSERC would include the Discovery Grants – Northern Research Supplement and the Collaborative Health Research Projects (CHRP).

Drug discovery is a risky endeavor; diversification will be important for scientific success. Also critical, are strategic partnerships and community support.

We have estimated that this initiative altogether may represent funding that would add up to \$5M over 5 years. Chairs would represent \$2M, and dedicated HR and operational grants around ~\$3M. This figure is a conservative estimate and can substantially increase with an expansion in the scope of the research plans.

### Risk and Critical Success Factors

1. Drug discovery is a high risk endeavor; thousands of compounds generally need to be screened to identify drug leads. The bio-prospecting initiative will have to manage that risk, and will

- successfully do so to mitigate its risk through having several sub-programs such as sampling medicinal plants, soils, micro-organisms, etc.
2. Drug discovery is only as good as screening tools; NEORCC cell lines are certainly one critical success factor. Additional innovative tools should also be developed as well as strategic partnerships with leaders outside the region should be sought.
  3. The ability to identify potential medicine is very dependant on disease expertise and scientific excellence of the medical participants.
  4. Because this is a dispersed initiative that is Northern Ontario/Canadian in nature, cohesion and collaboration among all partners is critical for the success of this endeavor. The community buy-in is warranted, and leadership needed to keep stakeholders motivated in supporting the several activities.

### Steps to Move Forward

- Create the consortium for Bio-prospecting in Northern Ontario that would regroup the potential stakeholders in Northern Ontario
  - Those who have access to natural resources (herbal medicine, biomass, micro-organisms, etc.)
  - Those who have access to knowledge (Academics, Aboriginal leaders or knowledge owners)
  - Those who have access to technologies and expertise (databases, screening tools, purification expertise, analytical tools)
- Write a letter of intent for CFI
- Define the strategies and priorities for bio-prospecting
- Create an integrated and comprehensive research plan
- Create a commercialization strategy
- Apply for operating funds and pro-actively apply for the larger infrastructure needs
- Create the training program
- Initiate a small-scale pilot project using one source of sample to structure the team, establish methodologies, optimize the logistic and define more precisely actual needs for the large scale deployment of the initiative. Import best practices in sample collection, cataloging, and data management
- Plan the scale-up of the project to leverage all local resources for bio-prospecting
- Develop a detailed commercialization plan for both discovered drugs and for exporting expertise and capabilities
- Build infrastructures and acquire equipments
- Begin large scale bio-prospecting
- Evaluate discovered drug leads in pre-clinical studies
- Implement commercialization plan and identify potential partners

**Figure 19. Bio-Prospecting Initiative Timeline**

Bio-Prospecting Initiative	year 1-Q1	year 1-Q2	year 1-Q3	year 1-Q4	year 2	Year 3	Year 4	Year 5
Create the consortium for Bio-prospecting in Northern Ontario	█							
Write a letter of intent for CFI	█							
Define the strategies and priorities for bio-prospecting	█	█						
Create an integrated and comprehensive research plan		█						
Create a commercialization strategy		█						
Apply for operating funds and pro-actively apply for the larger infrastructure needs.		█						
Create the training program			█	█				
Initiate a small-scale pilot project			█	█	█			
Plan the scale-up of the project					█			
Develop a detailed commercialization plan					█			
Build infrastructures and acquire equipments					█			
Begin large scale bio-prospecting					█	█	█	█
Evaluate discovered drug leads in pre-clinical studies							█	█
Implement commercialization plan and identify potential partners								█

### 3. Collaborative Interdisciplinary Research and Commercialization Fund Initiative

#### *Mid-term initiative*

#### Summary

Innovation occurs when interdisciplinary research intersects with highly qualified graduate students and research personnel.

Innovation occurs when interdisciplinary research intersects with highly qualified graduate students and research personnel. Northern Ontario has historically lacked some of the enablers to promote these strong collaborations, and now desires to aid in promoting academic excellence. To achieve this, a specific research fund could be created that would promote collaborations, and attract highly qualified graduate students, post-doctoral fellows and researchers while creating innovative training regimes to further serve to promote interactions. Though a multi phased process, this fund would also enable the development research projects past the proof of concept stages and towards early commercial potential. Therefore internationally competitive science would be promoted while commercial opportunities would be identified and brought forward over a 5-10 year time horizon.

#### Vision

The Northern Research Network Fund would bring together researchers, and their associated graduate students, to foster innovation in areas directly relevant to Northern communities.

#### Introduction

Northern Ontario's geography is not conducive to collaborative health sciences and innovation between communities. Often observed are research groups attempting to either work in isolation rather than collaborate. Attempting to drive researchers towards interdisciplinary collaborative research requires resources (usually grant money), champions (usually principle investigators but often graduate students) and accountability for excellence. When combined, these factors can aid in driving not only a research agenda but also a potential commercialization while attracting highly qualified graduate students.

The central idea to bridge the physical as well as scientific gaps, a collaborative research fund for health research and commercialization is proposed. This fund would be modeled after the national Centres of Excellence program. The centres of excellence type programs aid in bringing together researchers across the country to work on specific issues and also to develop sustainable research opportunities in either the private or public sectors.

A research fund would aid in promoting collaborations driving towards excellence in research.

One of the main objectives of this fund will be to promote collaborations within Northern Ontario as well as international collaborations with centres of academic excellence. In order to collaborate one must first identify research opportunities within Northern Ontario. Once identified, competitive applications must be sought from the fund by collaborative groups. Upon a successful award, graduate students who are going to carry out the majority of the research must be attracted to the environment, trained properly while

developing their own competitive career paths. These activities should combine to result in excellence in innovation.

The Northern Network can have the ability, through targeted funding and specific requirements for the granting process, to direct groups towards certain outcomes. These outcomes can include:

- commercialization
- academic excellence
- Northern and international collaborations

Once the strategic directions are agreed upon, it will take many years (or even a decade) to begin to realize the rewards in putting forth such an initiative. This is due, in part, to the long research and development cycles within the life sciences.

### The Market Need

Competition for research dollars does not solely reside within the confines of CIHR, NSERC, CFI, etc but exists within a global network of research science. Research is competitive and requires larger collaborations to come together and quickly solve key questions before large, competitive and well funded research groups are able to create the first discovery. By becoming innovators, research groups can have the option to file invention disclosures and publish in high quality journals. What is ultimately required is for researchers to attract enough funding to build momentum. For example, UBC is the most successful Canadian University for patenting technology<sup>26</sup> and has approximately \$2 million in research funding (industry and government sponsored) for every invention disclosure<sup>27</sup>. Each disclosure will not be filed for a patent and thus the research funds in order to create a successful patent are considerable.

There are numerous research projects occurring across Northern Ontario. These projects are in universities, colleges and hospitals. Attempting to compete against larger institutions will be difficult. By creating the infrastructure and incentive for research groups to work together, larger and more competitive research groups can be formed. This will assist in the drive to become first to discover, while maintaining the highest standards in research, is critical in developing a research economy. Only when a consistent track record of publications in high quality journals<sup>28</sup> scientist will be able to attract:

- more funding
- high quality graduate students and post doctoral fellows
- greater opportunities for commercialization of technology

In order accomplish these goals, researchers within Northern Ontario can be given the opportunity to capitalize on many of its unique assets. By bringing diverse groups of people together, a unique scientific proposition can be created that will assist in developing academic excellence. The creation of an environment for academic excellence while promoting innovation and

A concerted effort is required to initiate and drive a research and innovation agenda.

<sup>26</sup> The Scientist, June 20<sup>th</sup> 2005

<sup>27</sup> <http://www.uilo.ubc.ca/>

<sup>28</sup> e.g. impact factor greater than seven

collaboration will aid in fostering research within a healthcare research network.

Large research funds alone do not aid in commercializing technology. Private funding groups, such as seed, angel and venture capital investors, are required to provide the necessary capital to move commercial projects forward in a timely manner before patent expiration occurs. These types of investors attempt to offset technology risk by minimizing risk in other areas such as management risk. Commercializing healthcare and life science technologies in Northern Ontario is perceived as a risk due to:

- limited numbers of individuals with life science management experience
- limited number of investors for future funding rounds
- limited local infrastructure may be missing (for specific equipment)
- limited numbers of highly qualified personnel
- retention issues

Creation of a fund that enables technologies to progress to a later stage of development will offset some of the technology risk associated with new discoveries. By reducing technology risk, investments into specific discoveries would be more attractive. Therefore this fund would be aimed at aiding researchers to:

- become more competitive internationally
- attempt riskier projects that may yield higher rewards
- create a clear long term path for discovery and commercialization
- attract competitive and highly qualified graduate students
- upgrade the skills of principle investigators, post doctoral fellows and graduate students
- promote collaborations across institutions, cities and disciplines

## Background

### Strategy

The fund's central role would bring research groups together in order to advance novel, interdisciplinary and/or collaborative projects while continually advancing the quality of the science. This fund would have the following objectives:

- **Research**

Creation of an academic research fund with three distinct phases, each phase moving from academic-type research to potential commercialization and/or nationally competitive research.

- *Phase 1: Years 1-3.* Smaller amounts of funding for a considerable number of projects that are focused on collaboration across Northern Ontario (cannot be within one city), Canada and also internationally. This funding is intended to allow groups to start the collaborations and to gather, analyze and publish data in new areas.

Innovation involves attracting highly qualified personnel, providing innovative learning environments and many opportunities for interaction.

Projects with commercial applicability will be funded but will not require this to be demonstrated.

- *Phase II:* Years 3-6. Researchers at this stage will have demonstrated their progress in developing their projects and will have generated publications and/or intellectual property protection. Projects without key data or limited commercial applicability will most likely not move forward. This will be an opportunity to also fund new projects deemed to have progress with Phase I funding. Projects with commercial opportunities for Northern Ontario will be provided more funding to build on previous work.
- *Phase III:* Years 6-9. Research projects that have demonstrated international competitiveness while demonstrating a potential clear commercial opportunity. The number of groups being funded at this stage is deemed to be less but the individual grant sizes will be larger.

- **Students**

Development of a Northern Graduate Student Academic Network where nationally competitive graduate students would join the network and:

- receive funding to “top up” national scholarships to compete against programs such as UBC or U of T who top up nationally funded students and waive graduate tuition;
- develop specialized training courses that students will attend once a year in different cities; these courses will highlight the capabilities of a city as well as foster graduate student interaction. These courses would include such topics as scientific techniques (e.g. tissue culture, genomics), humanities and skills (e.g. research ethics, grant writing and project management) and commercialization (e.g. business plan writing).

- **Conferences**

Participating researchers and graduate students hold conferences every other year where new collaborations are formed and researchers become aware of ongoing projects within the year. Before the fund would start a Northern Ontario conference would be held for the life sciences. This would enable everyone to meet and learn about ongoing projects and capabilities. Every other year a Northern Ontario/Canadian conference can be held to demonstrate progress and foster interactions with researchers and graduate students.

- **Awareness**

To apply to this network, researchers would be required to apply for all funds through an interactive internet portal. There would be limited or no paper applications. The advantage of this would be the ability to have every research project and student profile instantly accessible by Northern researchers. Developing a paperless application process with a searchable web interface

could be attractive for other institutions or smaller funding agencies as a purchasable product nationally and internationally. This could demonstrate how funding such an organization could generate revenue that would offset (or cover) the cost of development and maintenance.

#### Roles and responsibilities

- **Governance and oversight**

A scientific governing board (6 members from clinical and basic science research and 2 members from the funding agency) will be required to oversee the granting process. This board would give direction to the granting process, workshop topic creation and conference timing. It is likely that this group would be required to meet once a year.

- **Administration**

The idea of creating such a fund is not to increase administrative burden. However, it is recognized that significant coordination will be required for:

- granting process (every three years)
- conferences (every other year)
- studentships (every year)
- workshops (every year)

It is envisioned that two full time staff and a senior manager (part time) will be required to manage and coordinate all of these process and that this would be coordinated, in whole or in part, within FedNor. The resources could be shared with other programs in FedNor in order to keep costs down.

The individual workshop topics should be proposed by the board but individual cities or institutions would put forth budgets and coordinate events. Some workshops, such as research ethics and project management, occur via remote learning using existing extensive video conferencing capabilities.

- **Grant and studentship review**

Reviewers would come from Northern Ontario, national and international sources. They would comprise specialists in specific scientific fields as well as experts in commercialization. This review process in Phase I is intended to allow research to be facilitated/developed and not hindered by the lack of preliminary data. It is only in Phases II and III that the review process should focus on *progress* made (publications and/or patents filed) and therefore a given research project's merit is internationally judged.

### Regional Assets

Universities and colleges:

- Algoma University College
- Lakehead University
- Lake Superior State University (LSSU)
- Laurentian
- Nipissing University
- Northern Ontario School of Medicine
- Canadore College
- Collège Boréal's
- Confederation College
- Canadian Career College,
- Cambrian College
- Collège Boréal
- Georgian College
- Hearst University College
- Northern College
- Sault College of Applied Arts and Technology (Sault College)

The region has numerous universities, colleges and health institutions to draw upon to initiate collaborative projects.

Research Initiatives:

- Paleo-DNA Laboratory
- The Centre for Rural and Northern Health Research (CRaNHR)
- Group Health Centre (Sault Ste. Marie)
- Northeastern Ontario Regional Cancer Centre (NEORCC)
- Northwestern Ontario Cancer Research Institute (NWOCRI)
- Regenerative Medicine Research Institute and Tissue Bank Initiative (Thunder Bay)
- North Bay Research (North Bay)
- Upper Lakes Environmental Research Network (ULERN)
- Westlink and technology transfer offices at the Lakehead and Laurentian Universities

### Financial Strategy

Undertaking a venture such as this can be broken down as follows per year:

**Table 5. Program Funding**

Program	Cost	Total for 11 years
Administration and support	\$100,000 per year	\$1,100,000
Creation of operational plan	\$75,000	\$75,000
Phase I (3 years)	1,250,000	4,000,000
Phase II (3 years)	1,250,000	4,000,000
Phase III (3 years)	1,250,000	4,000,000
Studentship supplements	400,000	5,500,000
Training programs	100,000	1,100,000
Conferences (five)	200,000	1,000,000
<b>Total</b>		<b>20,775,000</b>

To fund such an extensive program strictly focused in Northern Ontario, FedNor and NOHFCC would be required to fund parts of this initiative. The

universities and collages could support with in kind contribution with facilities and FTEs on a part time basis.

**Risk and Critical Success Factors**

A large amount of Northern Ontario/Canadian support will be required for this initiative to be successful. This should be discussed with participating institutions, universities and collages to ensure that they are aligned and willing to provide monetary or in kind contributions. Critical success factors will include:

- participation of wide variety of research groups and academic students
- projects brought forward are competitive locally in Phase I, nationally competitive in Phase II and internationally competitive in Phase III.
- enough projects exist to warrant Phases II and III

**Steps to Move Forward**

**Figure 20. Collaborative Research and Commercialization Fund Timeline**

Collaborative Research and Commercialization Fund	Year 1 Q1	Year 1 Q2	Year 1 Q3	Year 1 Q4	Year 2 H1	Year 2 H2	Year 3-5	Year 6-8	Year 9-11
<b>Step 1: Proposal creation</b>	[Timeline bar]								
Creation of a board	[Timeline bar]								
Design governance and refine requirements	[Timeline bar]								
Consult local stakeholders to ensure buy in	[Timeline bar]								
Creation of an operational plan	[Timeline bar]								
Work with potential funding partners to ensure project is within mandate	[Timeline bar]								
Put forth a proposal	[Timeline bar]								
<b>Step 2: Implementation</b>	[Timeline bar]								
Organization of confrence and grant process	[Timeline bar]								
Web portal development	[Timeline bar]								
Conference kickoff	[Timeline bar]								
Phase I grant	[Timeline bar]								
Phase II grant	[Timeline bar]								
Phase III grant	[Timeline bar]								
Organizing and planning Student workshops	[Timeline bar]								
Create workshops	[Timeline bar]								

## 4. Research Chairs and Fellowships Initiative

*Short- to mid-term initiative*

### Summary

The initiatives proposed in the current strategy for developing the health sector will require leaders and highly qualified personnel. These resources are comparatively sparse in Northern Ontario, and therefore significant initiatives are warranted to attract, retain and support current and future local leaders. Further support is also warranted to attract and retain professional staff and students. The research chairs and fellowships initiative is a human resource strategy that will accompany and support the featured projects proposed in this document. It proposes to create high profile positions for leaders in the strategic fields of bio-prospecting and genomics/proteomics. It further proposes a fellowship program that will support students through fellowship and fellowship supplements for graduate students. Its vision is to make the region a rewarding environment to pursue a career in medical research. By creating chairs and fellowships, it will provide strong incentives to retain and attract true leaders to champion Northern Ontario featured projects. Faculty representatives will oversee that chairs and fellowships are available to attract, retain, and foster local champions for its initiatives. Chair availabilities and fellowships will need to be advertised to reach and attract leaders from beyond the region. In order to attract true leaders, the program should be aligned with research support and a dynamic environment in which to conduct science.

### Vision

To provide Northern Ontario academics involved in medical research with outstanding support to make the region a rewarding environment to pursue a career in research.

### Mission

Provide academic researchers and graduate students with:

- Salary funding through the Canada Research Chairs (CRC) program
- Competitive fellowships, scholarships and bursaries
- Bursary supplements to graduate students receiving federal or provincial fellowships
- Relocation expenses

### The Market Need

The two universities in Northern Ontario have been successful at attracting several key scientists to lead medical research in the region. However, the medical research sector is a highly competitive market and very dynamic as well. Scientists tend to be career-driven and are generally quite mobile. Northern Ontario thus needs to be mindful of this environment and cater to its scientists' needs for career progression and gratification. Creating chairs to lead the strategic scientific endeavors represents a strong incentive to retain and attract true leaders to champion Northern Ontario featured projects in health research.

To make the region a rewarding environment to pursue a career in medical research.

Creating chairs and fellowships represents a strong incentive to retain and attract true leaders to champion Northern Ontario featured projects.

Across Canada and in the US, medical research manpower is normally composed of graduate students. In Northern Ontario, however, there are few students graduating in molecular medicine-related fields (biochemistry, microbiology, molecular biology, molecular genetics, etc.), and many potential students may be tempted to pursue graduate studies outside of the region. To retain these students and attract others from other institutions, effective marketing and bargaining tools (communication and incentive programs) are necessary.

## Background

### Objectives

- To apply to CRC for a tier 1 chair in bio-prospecting
- To apply to CRC for a tier 2 chair in genomics/ proteomics
- To explore other chair opportunities, with CRC or philanthropic organizations (e.g. disease foundations, Pharmaceutical companies, etc.)
- To create a Northern Ontario fund for supporting graduate students with competitive bursaries and fellowships, and supplements for awardees of national competitions

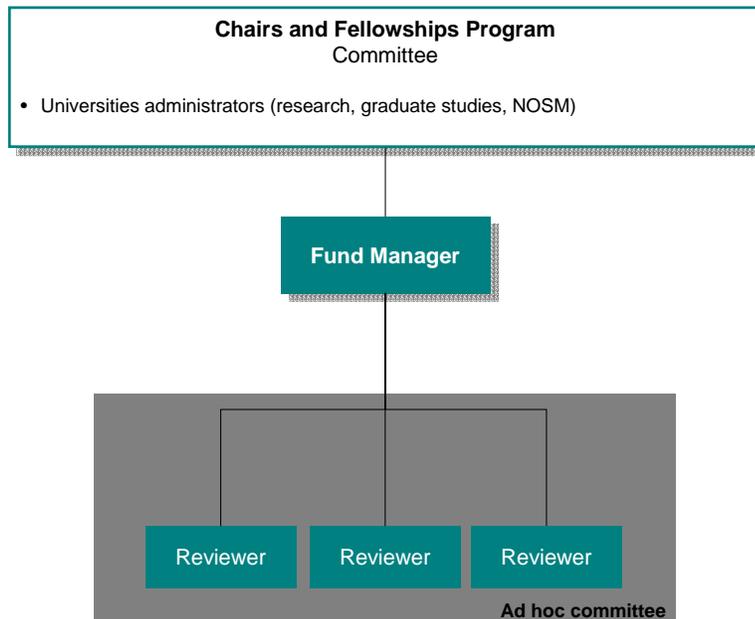
### Strategy

#### Roles and responsibilities

The Chair and Fellowship program should be overseen by a committee of universities administrators for research, graduate studies, and NOSM. The committee will appoint a faculty member that would be responsible to manage the program communication (advertising, and recruiting), applications collection, creating objective review panels, and awarding the grants. Furthermore, the committee will also take the responsibility to apply for Chair funding for its strategic projects.

Faculty representatives will oversee that Chairs and Fellowship are available to attract, retain and foster local champions.

**Figure 21. Chairs and Fellowships Program Committee**



Chairs availabilities and fellowships need to be advertised to reach and attract leaders from beyond the region.

### Processes and communications

The committee's first mandate would be to define Chair opportunities to be sought beyond bio-prospecting and genomics/proteomics, as well as the characteristics of the fellowship and bursary program. Active marketing of the Chair and Fellowship program is critical. The committee and its manager should make sure that the target community is aware of the opportunities in the region and that they appreciate the advantages and benefits of these opportunities. Furthermore, incentives should be weighted to maximize funds usage; for instance, it would be important to determine how much fellowships and fellowship supplements should amount to in order to be effective incentives without limiting the number of awards given. A starting point should be 20% above CIHR rates. The fund manager should recruit three independent reviewers from outside Northern Ontario to evaluate candidates and attribute them a rank. Then the fund manager with the committee would award the fellowships according to the ranking and its internal rules (i.e. balanced distribution of awards across the region, across disciplines, etc.)

### Fund

Winning chair funding from external agencies and organizations and managing fellowship and bursaries should be a faculty effort on the universities behalf and should constitute an extension to the mandate of current officers and staff in both universities. The funding for the bursaries and fellowship, on the other hand, should be raised from partners that have interest in the Northern Ontario or medical science i.e. the Northern Ontario Heritage Fund Corporation (NOHFCC), FedNor, NOSM, the Regional Innovation Network (RIN), municipalities, universities, philanthropists (including pharmaceuticals company philanthropic arms). The fund needs is estimated at \$1,000,000 a year to support about 20 graduate students and 10 post-doctoral fellows.

## **Risk and Critical Success Factors**

Chairs and fellowships should be aligned with proper research supports and a dynamic environment to attract true leaders.

The Chair and Fellowship programs are meant to attract and retained highly qualified personnel. While they are designed to create effective incentives, it is critical that these opportunities are well advertised in order to ascertain that the most competitive candidates are being solicited. Also critical is that infrastructure and organizational support is available for recruits to thrive. For scientific leaders, having access to research infrastructure and support is as much an incentive as is a generous income. A program that would provide generous personal benefits (chairs, bursary, fellowship, travel, relocation); but a poor research environment would more likely attract opportunists than champions.

## **Steps to Move Forward**

- Create the Chair and Fellowship committee
- Determine the program priorities and selection criteria for awards
- Appoint the fund manager
- Recruit funding partners and applied for Chair funding
- Create a marketing plan for awards
- Launch awards program

- Fund first students and Fellow

**Figure 22. Research Chairs and Fellowships Timeline**

Research Chairs and Fellowships	Year 1-Q1	Year 1-Q2	Year 1-Q3	Year 1-Q4	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
Create the Chair and Fellowship committee													
Determine the program priorities and selection criteria for awards													
Appoint the fund manager													
Recruit funding partners and applied for Chair funding													
Create a marketing plan for awards													
Launch awards program													
Fund first students and Fellow													

### III. Commercialization Strategy

This is the third and final strategic plan and consists of five initiatives, which are listed below.

1. Regionally Focused Venture Seed Fund
2. Direct Investment into Academic Labs by Private bioscience Companies
3. Network of Technology Transfer Offices
4. Research Parks and Incubator Network
5. Liberal, Harmonized Intellectual Property Policies

#### 1. Regionally Focused Venture Seed Fund

*Long-term initiative*

##### Summary

The current Northern Ontario economic strategy has put an important emphasis on the development of the health and biotechnology sector in the region (e.g. NOBI). The health research and biotechnology industry have fairly unique business models where risks are generally high and timelines for returns generally long. For this industry to develop and prosper, access to 'risk money' is crucial. It is thus very important that such funding capabilities be developed in the Northern Ontario region to foster the potential economic outcomes of the current initiatives and to develop the health industry. The aim of the proposed fund is to provide seed funds to Northern Ontario biomedical entrepreneurs that have promising ventures with potential for high economic returns. Northern Ontario entrepreneurs currently have very little access to funds for risky endeavors such as those in the biomedical and biotechnology sector. With a capital of \$2.5M, the fund will provide seed financing of \$100K to \$1M, with an investment horizon of 5 years. In coordination with an advisory board a fund manager will evaluate funding opportunities and secure potential follow on investments from key VC partners. To mitigate the increased financial risk due to the challenging environment, the fund will comprise 50% public equity and the fund manager will develop close relationships with local stakeholders and with VCs in Toronto through, for example, MaRS. Success factors depend on the ability to build an entrepreneurial culture that is biotech savvy, to stimulate a critical mass of opportunities, and to foster a pool of human resource for the developing industry.

##### Vision

The regionally focused venture seed fund will provide financial assistance to Northern Ontario biomedical entrepreneurs that have promising ventures with potential for high economic return and global reach.

## Mission

The mission of a regionally-focused venture seed fund is to provide financing for high reward start-up companies to leverage biomedical assets of Northern Ontario in activities such as:

- Biomedical services (including diagnostics services, contract research services, genetic screening, etc.)
- Biomedical tools (including cell lines, animal models, bio-products, devices, methods, etc.)
- Drug discovery (new promising medicine, diagnostics, biomarkers, etc.)

## The Market Need

Currently, Northern Ontario does not have resident venture capital firms. This is not unusual as all venture capital firms in Ontario are located in Toronto (albeit a few are located in London). Furthermore, Canadian VCs are generally very unlikely to invest in regions that are far from their headquarters. This implies that Northern Ontario entrepreneurs have very little access to funds for risky endeavors such as those in the biomedical and biotechnology sector. Yet, there are business opportunities in the region as seen in Molecular Word, Genesis Genomics and PaleoDNA, three biotechnology companies that were started in Thunder Bay. Noteworthy, Genesis Genomics is funded by a Toronto VC. Furthermore, with the proposed initiatives for developing the biomedical industry along with the new school of medicine, many more opportunities will arise. For these opportunities to become commercial venture in the region, local venture funds will need to be available.

Northern Ontario entrepreneurs have very little access to funds for risky endeavors such as those in the biomedical and biotechnology sector.

## Background

### Objectives

Traditionally, return expected from venture capital funds is in the range of 30%. To reach this goal, investments should target ventures with exceptional commercial potential. This regionally focused venture seed fund will especially cater to ventures at the proof of concept stage, and provide linkages with bigger funds to secure follow on financing for successful clients. Furthermore, investments should be targeted to projects that leverage the unique assets of the region. Examples include:

- Projects that require unique local resources such as biomass
- Projects that leverage the unique demography and culture of the region (e.g. clinical trials with specific population, or those that make strategic usage of the electronic patient registry)
- Projects that can rapidly saturate the market and use their strategic position to further expand beyond the region
- Projects that would help business partners to develop technologies away from the eye of the competition
- Projects that serve a need unique to remote communities

Moreover, by investing in projects that are dependent on local resources and assets, the fund would be aligned with regional communities' economic development objectives to create companies and jobs in the

With a capital of \$2.5M, the fund will provide seed financing of \$100K to \$1M, with an investment horizon of 5 years.

region. Thus, growing companies will have strategic interests in staying in the region.

The time horizon of investments should be 5 years and the fund should be structured as follows:

- \$2.5M total assets
- 5-10 seed funding (\$100K-\$200K) (\$1M)
- 1-2 strategic investment (\$500K-\$1M) (\$1M)
- 3% management fee (\$0.3M)
- Administration expenses (\$0.2M)

## Strategy

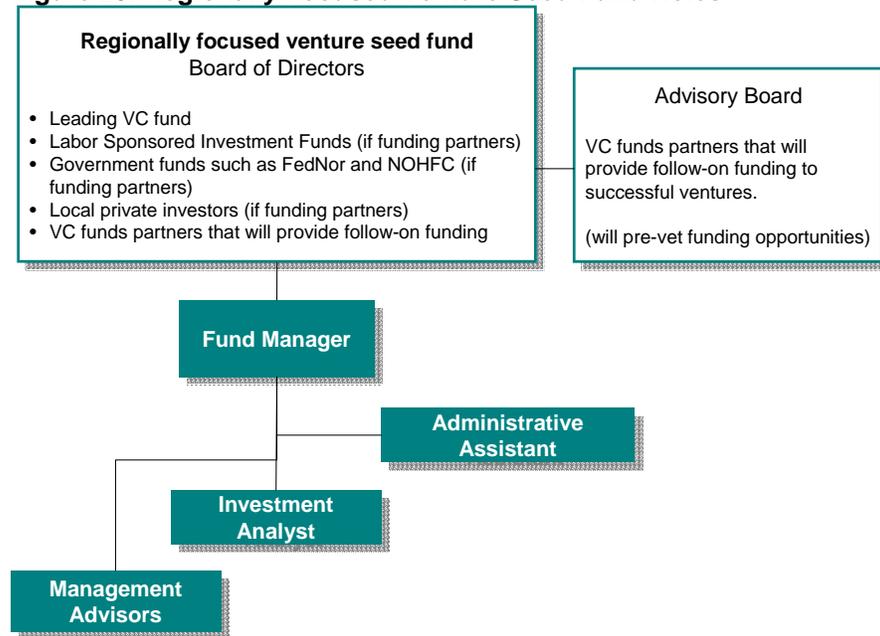
### Roles and responsibilities

The fund will be created from the contribution of a number of financing partners. These will constitute a board of directors that would appoint the fund manager. The board would be responsible to set the mandate of the fund and its limitations. It will also oversee that the manager respects the investment rules, that he/she makes sound investment decisions, that the clients are properly monitored, and that the clients are effectively supported with sound management advices.

The manager should be an experienced investor in the biotechnology and biomedical sectors. Among other roles, he/she will be responsible for evaluating investment opportunities and making investment decisions with the support of the advisory board (according to the fund rules set by the board of directors). The fund manager will also be responsible for monitoring and advising the clients, and ascertaining that clients meet their milestones and provide funds accordingly. Furthermore, the fund manager will be responsible for liaising, recruiting, or contracting any expertise that is deemed necessary to make sound decisions, to advise clients, and to support clients with managerial resources as needed.

In coordination with an advisory board the fund manager will evaluate funding opportunities and secure potential follow on investments from key VC partners.

**Figure 23. Regionally Focused Venture Seed Fund Roles**



Human resources

Biotechnology and biomedical fields are very complex and risky sectors where success depends on scientific excellence as well as complex market and regulatory forces. Evaluating an opportunity and managing its commercialization requires various expertise that are rarely found in one individual. The success of such ventures will thus require access to a panel of experts that will vary for each opportunity. A network of industry leaders, specialists and consultants need to be accessed to ascertain that appropriate expertise and advice would be readily available; this will be provided by the advisory board. At least one analyst should be supporting the fund manager in addition to an administrative assistant. Management advisors may be recruited by the fund to provide management support to clients as ventures are progressing or facing challenges.

Fund

The fund is envisioned to result from the participation of several shareholders. There are several reasons why VC firms are rarely found outside of major cities. These reasons will be further discussed in the risk and critical success factor section. Briefly, VC firms need proximity to their clients, a critical mass of investments, a pool of highly qualified personnel and relevant infrastructure. For these reasons, VC firms generally shy away from investing in remote areas. The regionally-focused venture seed fund will thus need some level of support to attract private financiers. An ideal model would be one that would bring the following investors:

- A well established VC fund that has a track record in investing in biomedical ventures that would take leadership in managing this fund
- Labor Sponsored Investment Funds
- Government funds (local, provincial, federal)
- Local private investors

To mitigate the increased financial risk due to the challenging environment, the fund will be 50% public equity.

The fund manager will develop a close relationship with the local stakeholders and VCs in Toronto e.g. MaRS.

### Processes and communications

The fund manager should create a tight link with technology transfer officers at the universities and colleges. It needs to nurture relationship with other VC funds, especially in the US and Toronto. One of the major challenges in the Canadian biomedical sector is that Venture Capitalists help companies starting up, but very little funding opportunities are available for follow-up investments.

Given that it takes generally several million dollars to bring a product to market, and that in the case of drug discovery, a few million will only bring the product to the Phase I clinical trial (\$100M more will be needed to bring the product to the market). Because of this stringent reality of the biomedical sector, venture capital funds need to plan a reasonable exit strategy i.e. an IPO, product licensing, merger, or substantial follow-on financing. It is currently ill advice for a drug discovery company to go public too early and tools companies have generally poor valuations. Therefore, a regionally focused venture seed fund will need to pro-actively create partnerships with VCs in the US and Toronto to increase chances that there will be follow-on money for their clients that successfully bring their technology forward. These partners constitute the advisory board, which will pre-vent the regionally focused venture seed fund potential investments, conduct a brief due diligence on opportunities, and provide recommendations. Presentations to VCs could be envisioned to be conducted through videoconferencing with VCs that would visit MaRS (Toronto) and entrepreneurs through NOSM videoconferencing (Sudbury, Thunder Bay). A positive recommendation from at least one potential follow-on partner should be a quasi requirement for funding a client. Advisory board partners would have the right to a first refusal for any follow-on funding they supported, given that they provide letters of intent for follow-on funding.

## Reward System

The driver for the fund and its shareholders and stakeholders is its rate of return on investment. Such a rate needs to be adjusted for the effective risk of venturing in this sector. Because the limited critical mass of the Northern Ontario region and a limited access to highly qualified human resources and infrastructures the perceived risk of venturing in Northern Ontario is higher. To mitigate that risk, public contribution to the fund should be provided to cover the heightened risk i.e. since the return on successful investment should not differ from major centers, the heighten risk need to be compensated by a lower cost of capital.

## Risk and Critical Success Factors

- Venture capital investors prefer to be in close proximity to their clients, because investing in a technological start up is not a passive process but warrants active supervision, coaching, and supporting management teams. This is why it is so critical that a local link with VC funds be established in the region. However, because of the active roles of the fund in monitoring and providing advices to clients, it is critical that the team be mobile across Northern Ontario. It would

Success factors depend on the ability to build an entrepreneurial culture that is biotech savvy, to stimulate a critical mass of opportunities, and to foster a pool of human resources for developing industry.

be further strategic for the fund manager to be giving seminars to student in management science about the biomedical industry as well as to the business community to help develop a culture and human resources to support their clients on the long term.

- Most ventures fail, and therefore VC investors have to mitigate their risk by diversifying their investment into a critical mass of projects with high potential return. It is critical that the fund manager and the board be strategic in the selection of project and ascertain that potential return warrants the risk taken. In a small community golden opportunities would be seldom, the fund should be pro-active i.e. networking with the scientific community as opposed to waiting for fund requests. The fund manager should try to identify opportunities and coach researchers in going forward with the opportunities, as well as build the right team for success.
- With limited fund availability, the fund manager needs to ascertain that there are likely exit opportunities. Such exit opportunities may mean company acquisition or asset acquisition. Given that the purpose of this fund is for the economic development of the region, the investment committee should be mindful to invest in ventures that have a strategic fit in the region, and that upon exit of the VC assets would be very likely to remain in the region.
- An important risk for growing biomedical firms in a remote area is to have access to the skilled personnel that they need. Coordination between the fund, NOSM and the universities should occur to assure that the skilled personnel is being trained in the region to support the growing industry. Furthermore, a human resource plan should be put in place with the municipalities to provide proper incentives to attract high profile personnel.

### **Steps to Move Forward**

- Create a local management team
- Get commitments for public funds to match 50% of private investment
- Approach potential private funding partners and VC partners for the advisory committee and follow-on financing.
- Create a fund of \$2.5M
- Evaluate local opportunities
- Invest in promising ventures
- Collect return at the exit from successful venture
- Reinvest in new ventures

**Figure 24. Regionally Focused Venture Seed Fund Timeline**

Regionally focused venture seed fund	Year 1-Q1	Year 1-Q2	Year 1-Q3	Year 1-Q4	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
Create a local management team													
Get public fund matching commitment													
Approach potential private funding partners													
Create a fund of \$2.5M													
Evaluate local opportunities													
Invest in promising ventures													
Collect return at the exit from successful venture													
Reinvest in new ventures													

## 2. Direct Investment into Academic Labs by Private Bioscience Companies

*Mid-term initiative*

### Summary

Beside educational purposes, research activities serve as an engine for innovation and long-term economic development. The latest advances in biomedical research have raised the field to a point where research outcomes can have immediate or short-term impacts on medical practices and drug discovery. This is why industry and academic research have grown closer together in the last decade. Northern Ontario's current and emerging assets in medical research thus provide the region with many commercial opportunities which should be leveraged to attract private funding in the ongoing research activities. Researchers in Northern Ontario are developing tools and making discoveries that may have value to the right private partner; the direct investment committee will provide local leadership in industry relation and global awareness of the region's value proposition. The direct investment strategy would be directed by a committee of experienced stakeholders that will bring together their experience and resources. The operations of this committee should be led by the united Technology Transfer Office partners. The direct investment initiative should required around \$100K for start up and assemble an operating budget of \$50K for initiatives and promotional activities.

### Vision

To create an effective link between international firms in the health sector and investigators in Northern Ontario.

### Mission

The mission of this initiative is to provide strategic thinking and resources that will catalyze the ability of local stakeholders to attract investments from international industry players into Northern Ontario health research activities and into its local commercial ventures.

### The Market Need

Research currently ongoing in the region, as well as the initiatives to be launched, as a result of this current strategic exercise bear several commercial opportunities that private companies may want to participate. In clinical research for instance, pharmaceutical companies are constantly searching for clinical investigators that can rapidly recruit patients for their studies. The patient profiles and rapidity of enrollment are key factors for the industry, and represents aspects where the region can provide a competitive advantage. In drug discovery, the pipelines of pharmaceutical companies are drying up and these firms are actively looking for new ways to develop or replenish these pipelines. Researchers in Northern Ontario are developing tools and making discoveries that may have significant value to the right private partner.

To provide local leadership in industry relation and global awareness of the region's value proposition.

Researchers in Northern Ontario are developing tools and making discoveries that may have value to the right private partners.

Moreover, the vast region of Northern Ontario presents several challenges in term of access to medical services. There is a need for innovative approaches to health service delivery as well as information technologies to empower health care professionals to provide high quality services in localities where there are no critical mass. These needs are generally unique to remote regions, and therefore, have not attracted the interest of investigators and entrepreneurs in the urban centres. This geographical dispersal renders these needs a unique opportunity for Northern Ontario to become a leader in this field.

## Background

### *Objectives*

- Catalyze the growth of clinical research contract in the region from pharmaceutical firms.
- Attract private funding for investigating, developing, or implementing health service delivery system in the region as well as health information system and tele-health.
- Attract the interest of private partners into bio-prospecting activities to be initiated through this plan.
- Attract private funding for epidemiological studies that will highlight health risk factors or genetic markers.
- Attract diagnostic and device firms to test and pilot their product in a region away from competitors' eye.
- Attract private investments in communication technologies for health service delivery in disperse environment.

### *Strategy*

#### *Roles and responsibilities*

The direct investment strategy should be led by the unified Technology Transfer Office (see below). While each direct investment will be the responsibility of the investigators or entrepreneurs that will received the funding, the Technology Transfer Office should support the local stakeholders in the following ways:

- By nurturing a vast network of relationships with international industry partners
- By pro-actively advertising Northern Ontario assets and capabilities
- By advising local investigators and entrepreneurs about potential opportunities
- By providing professional services support to investigators and entrepreneurs such as legal advice, contract drafting, management advice, support in negotiation, etc.

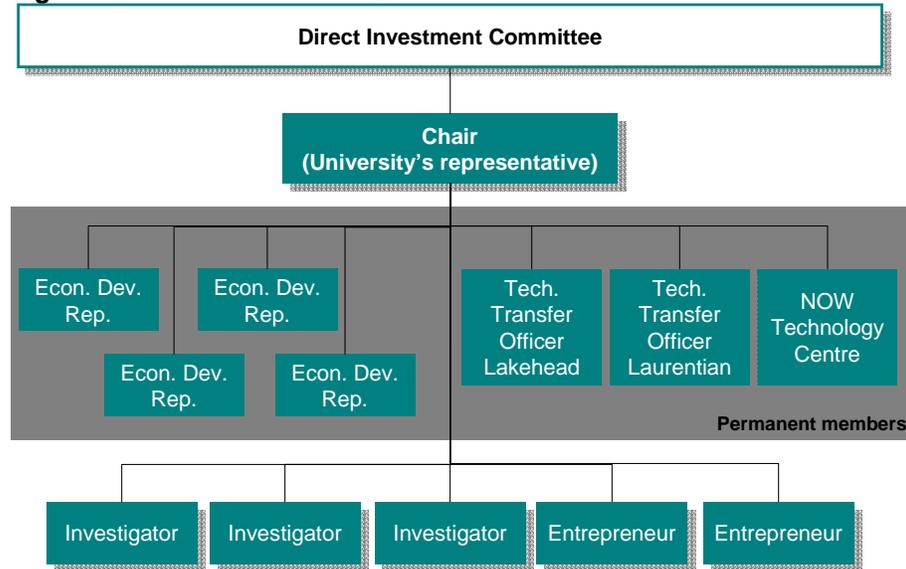
#### *Human resources*

A committee should be created that would be chaired by a university representative, and comprise of the regional technology transfer organizations' representatives, economic development representatives of Northern Ontario communities, and a subset of key investigators and entrepreneurs that have past experience with industry partners. The committee should be a two-tier committee with permanent members comprising of the technology transfer representatives and the economic development representatives. The

The direct investment operations should be led by the united Technology Transfer Office partners.

chair should be elected for a non-renewable two year term. The rest of the committee members should also serve non-renewable two year term mandates. The two-tier model is meant to prevent stakeholders from monopolizing the committee’s resources for their own needs.

**Figure 25. Direct Investment Committee**



The direct investment strategy would be directed by a committee of experienced stakeholders that will bring together their experience and resources.

Processes and communications

The committee will meet quarterly to discuss direct investments obtained, opportunities pending, and strategic and tactical considerations to successfully meet investigators and entrepreneurs needs. Built upon the committee members’ network with the industry, an expanding database of potential industry partners should be created and managed by the unified technology transfer office. The technology transfer officers will interface or initiate contacts between the investigators or entrepreneurs, and potential industry partners. The committee should also publish a quarterly news debrief to communicate to investigators and entrepreneurs about its activities, and ascertain that the community is constantly reminded of the direct investment support program, services available and its successes. The committee will leverage the human resource assets of the technology transfer office to support direct investment opportunities. In this respect the technology transfer office will act as a business development office.

**Regional Assets**

- The Intellectual Property Management Office (IPMO) at Laurentian University currently offers services that include partner search and negotiation support. It is envisioned that the IPMO will merge into a pan Northern Ontario technology transfer office.
- The Innovation Management Office (IMO) at Lakehead University also offers to its investigators, several services in regard to commercialization. It is envisioned that IMO will also become part of the pan Northern Ontario technology transfer office merger.

- The Northwestern Ontario Technology Centre acts as a catalyst that encourages co-operation with businesses. It also provides several commercialization services that can be leveraged for attracting direct investments
- The Regional Innovation Network (RIN) of the Northern Ontario Biotechnology Initiative will have three sector specialists and an Executive director located at MaRS (Toronto). This network would be a strategic contributor of business and networking resources.
- Beside contributing to the committee assets, the clinical trials networks and the clinical investigator teams will also be the first beneficiaries of direct investments as they currently are; namely the ICR Discoveries Institute of Cancer Research, the Northeastern Ontario Regional Cancer Centre, NEUREKA!, Group health Centre (SAULT STE MARIE), Northgate Medical Clinic, ProBity Medical Research, and North Bay Research, as well as other clinical research teams.
- Several health-focused basic scientists in Lakehead and Laurentian universities would also be both contributors and beneficiaries of the committee services.
- The bio-prospecting initiative to be launched as a result of this endeavor would likely become a beneficiary of the direct investment program.
- Hospital facilities that can support device testing and development could also benefit from the committee's services.

### Financial Strategy

Financial resources would be needed for administrative purposes and events management. It is envisioned that a starting fund of ~\$100K be invested by the constituents of the committee, with the committee's further operation needs being estimated at ~50K\$/year. This estimate only includes committee activities. Services provided through partners should be self-sufficient by charging a fee for services on a non-for-profit basis.

### Risk and Critical Success Factors

The success of this initiative relies on the effective centralization of regional resources in business development for medical science. For the committee to be successful, it further needs:

- To be highly visible to the investigators and entrepreneurs of the Northern Ontario health sector
- To gain credibility toward its stakeholders
- To successfully build long term relationship with industry decision-makers

The more early wins the committee accumulates, the more buy-in it will get from its members. Noteworthy, the networking database will primarily be derived from the current relationships that investigators have established with the industry; it is thus critical that the great majority of regional stakeholders come aboard this initiative.

The direct investment initiative should require around \$100K for start up and assemble an operating budget of \$50K for initiatives and promotional activities.

### Steps to Move Forward

- Bring together technology transfer directors including the Lakehead University IMO, Laurentian University IPMO, and the Northwestern Ontario Technology Centre. These stakeholders will champion the initiative and seek to integrate it with the Network of technology transfer office initiative.
- Rally the investigators and entrepreneurs to become members. It is critical that the majority of the investigators susceptible to raise direct investment be aboard this initiative. They will both bring resources and purposes to this endeavor.
- Agree on needed funding to launch the initiative and get it running for the first year. Also negotiate the partners' contributions.
- Hold a first meeting to create the committee. A quorum of recruited members should be brought together to vote on the constitution of the committee.
- Hold a first executive meeting to create strategies and tactics that will enable the committee to meet its goals.
- Initiate communication activities, i.e. general meetings, news debriefs, and consultations with investigators and prospective industry partners.
- Successfully bring in new direct investments for the region's initiatives and research activities.

**Figure 26. Direct Investment Strategy Timeline**

Direct Investment Strategy	Year 1-Q1	Year 1-Q2	Year 1-Q3	Year 1-Q4	year 2	year 3	year 4	year 5	year 6	year 7	year 8	year 9	year 10
Bring together technology transfer directors													
Rally the investigators and entrepreneurs to become members													
Establish starting fund													
Hold first meeting to create the committee													
Hold first executive meeting to create strategies and tactics													
Initiate communication activities													
Successfully bring new direct investment													

### 3. Network of Technology Transfer Offices

*Mid-term initiative*

#### Summary

Provided that additional investments proposed for biomedical research are available in Northern Ontario, an increasing number of commercial opportunities are likely to arise. To best seize these opportunities, effective technology transfer processes should be in place and resources made available. Such a function requires access to several professionals such as corporate lawyers, intellectual property specialists, and business development professionals. The task of technology transfer is a daunting one that requires skills that warrant a multi-disciplinary team.

However, such a team of highly qualified professionals needs to be leveraged through a large enough portfolio of technological opportunities. Given the limited volume of technology in the several Northern Ontario institutions, there is not a critical mass that justifies creating such a team in every institution. The context thus warrants the creation of a network of technology transfer professionals that would share resources to oversee the larger portfolio of Northern Ontario technological innovations. This initiative thus aims at bringing together the regional resources in technology transfer to leverage highly qualified personnel through the larger portfolio. It is imperative that resources and processes be effectively deployed in the region to empower investigators and entrepreneurs to actualize their commercial opportunities. For this endeavor to succeed, it will need a genuine buy-in from the IMO and IPMO; a buy in that will be obtained by empowering these organizations through a larger more centralized one that brings greater success to its partnering offices.

#### Vision

The Network of Northern Ontario Technology Transfer Offices will bring together the regional resources in technology transfer to leverage highly qualified personnel through the larger portfolio of Northern Ontario innovations and to offer a unique storefront to its stakeholders.

#### Mission

The Network of Northern Ontario Technology Transfer Offices will have the responsibility to provide access to highly qualified professionals in all relevant spheres of expertise, and to provide assistance and services to all Northern Ontario investigators in regard to the commercialization process of innovative technologies. The network will provide services and assistance relating to:

- Advice on disclosure restrictions for new discoveries
- Evaluation of patentability
- Filing patents
- Evaluating market opportunities
- Identification of potential technology receptors
- Negotiation with industry

To bring together the regional resources in technology transfer to leverage highly qualified personnel through the larger portfolio.

Additionally, the network should organize educational as well as networking events, and ascertain the visibility of Northern Ontario technological opportunities to outside parties, including industry stakeholders.

It is imperative that resources and processes be effectively deployed in the region to empower investigators and entrepreneurs to actualize their commercial opportunities.

## The Market Need

The two Northern Ontario universities and the new Northern Ontario School of Medicine are three important drivers for innovation. Several biotechnology and biomedical companies have already spun-off from academic research performed in Northern Ontario. Moreover, consultations with researchers in Northern Ontario have revealed that there are a great number of commercial opportunities emerging from research undergoing in the region. In addition to current activities, the investments proposed as part of the new strategic direction for the development of the biomedical industry in Northern Ontario, will substantially raise the number of opportunities in the near future. It is therefore imperative that resources and processes be effectively deployed in the region to empower investigators and entrepreneurs to actualize these opportunities.

## Background

### Objectives

- To create a network that will share the larger portfolio of Northern Ontario technologies. Consequently, by building a critical mass of technologies and by sharing professional resources, the network's stakeholders will be able to recruit several highly specialized professionals that will share their experience and unique perspective on each file.
- To provide high quality professional services to investigators in regard to the commercialization of their innovations.
- To educate investigators about the commercialization process and its imperatives.
- To create networking events that will strengthen relationships with the industry, bring visibility to Northern Ontario assets outside of the region, and initiate partnership among industry and local investigators.

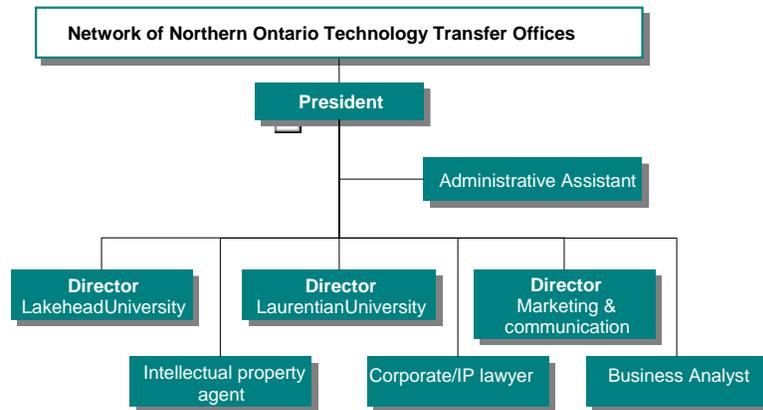
## Strategy

### Roles and responsibilities

The Network of Northern Ontario Technology Transfer Offices should be directed by a university administrator that is appointed by consensus from both universities. The president's responsibilities will be to bring leadership, strategic directions and oversight to the network's operations. The head of the Innovation Management Office (IMO) at Lakehead University and the Intellectual Property Management Office (IPMO) at Laurentian University should be appointed as Regional Directors whose roles would be three-fold: 1) to represent their institutions and serve as a liaison between their investigators and the network; 2) to provide the network with their expertise, know-how, and resources; and 3) to provide support to the president in overseeing and implementing Northern Ontario/Canadian initiatives. The Director of Marketing & Communication would be responsible for managing the storefront of

the network (web site, news briefs, pamphlets, etc.) as well as educational and networking events.

**Figure 27. Network of Northern Ontario Technology Transfer Offices**



An effective technology transfer function requires a variety of skills and knowledge. A balanced team would include business development officers, an intellectual property agent or lawyer, a corporate lawyer and a business analyst.

Human resources

An effective technology transfer function requires a variety of skills and knowledge. A balanced team would include business development officers, an intellectual property agent or lawyer, a corporate lawyer and a business analyst. Depending on the volume of innovations and opportunities for evaluation, the need for specialists such as the intellectual property agent and corporate lawyer may not warrant full-time positions. Alternatively, these functions could be subcontracted. Subcontracting based on a long-term retainer agreement should be favored over punctual contracts to create continuity in the process, and to minimize the administrative burden associated with evaluating and negotiating contract organizations.

Processes and communications

Opportunity evaluation should be discussed in committee meetings that include the regional directors, the specialists as well as the investigators. The decision around a technology evaluation warrants a comprehensive evaluation of the technology from a scientific, legal and business perspective. Therefore, opportunities should be presented in committee meetings, briefly discussed, and submitted for analysis when deemed appropriate. Analysis results from each perspective should be presented and discussed at an ulterior meeting where the decision as to whether to proceed to the next step or not should be taken.

The network should also organize seminars and educational material to inform investigators about technology commercialization, as well as how the network can provide assistance. It should also organize networking events that would allow investigators to meet with industry representatives to present their technologies and create an awareness of industry needs and processes.

While the network will manage the Northern Ontario/Canadian portfolio of technology, it will not own any of the intellectual property. The network would have a mandate of service provider for its constituents.

### Reward System

The network team would find value in this initiative if they feel empowered by the high caliber team which will help them to achieve success. Similarly, the stakeholders and investigators will value the initiative if they feel that it has improved their awareness around commercialization opportunities, provided rapid access to high quality advices, and helped them to succeed.

### Regional Assets

- The Innovation Management Office (IMO) at Lakehead University would be one of the founding organizations of the network. It would bring its resources and know-how to the network.
- The Intellectual Property Management Office (IPMO) at Laurentian University would be the other founding organization of the network, and bring its resources and know-how to the network.
- The Northwestern Ontario Technology Centre is a resourceful organization that could provide support and resources to the network as an external partner.
- The Westlink network already includes Lakehead University. This large and dynamic network could also provide support to the Network of Northern Ontario Technology Transfer Offices.

### Financial Strategy

The Network of Northern Ontario Technology Transfer Offices funding should proceed in two phases: 1) seed funding; and 2) operational funding. The seed funding should be provided by the two founding organizations, namely the IMO and IPMO. However, it would be possible to access external grants to support this endeavor through program such as the IPM program from the NSERC which provides funding for institutions to coordinate their approaches and activities around technology transfer on a local, regional and national basis. The last competition was in March 2005, and the next competition is scheduled for 2008. Fundings are generally provided for 3 year terms and are expected to range from \$100,000 to \$400,000. The NSERC as well as the CIHR, further offer financial support for business development trainees. The next competition for the CIHR Commercialization Management Grants is in January 2006.

The network's operations should be self-sustainable through fee-for-service model within a non-for-profit business model. It is not excluded that the network will negotiate for a percentage of the outcomes, such as licenses' revenue, contracts' revenue, etc. This additional income should then be directed toward:

- Reducing service costs
- Undertaking special initiatives
- Creating grants to support entrepreneurship
- Providing bonuses to the network officers

For this endeavor to succeed it needs a genuine buy-in from the IMO and IPMO. This buy-in will be obtained by empowering these organizations via success experiences through development of critical mass of resources and expertise.

Start-up fees and operations costs are estimated at ~\$100,000 and \$250,000 respectively.

**Risk and Critical Success Factors**

For this endeavor to succeed it needs a genuine buy-in from the IMO and IPMO and their respective university administrators. This initiative should be piloted by the heads of these two offices with the aim to empower themselves with a greater organization. This initiative should not be set to dilute the directors’ powers but to empower them with greater resources.

**Steps to Move Forward**

- To create the Network of Northern Ontario Technology Transfer Offices that will share the larger portfolio of Northern Ontario technologies and resources.
- To plan the re-organization of local resources:
  - Defining the participants’ roles in the network
  - Identifying the expertise and resource gaps
  - Drafting a plan for creating the network and streamlining its activities to meet individual institutions needs
- To implement the re-organization.
- To create an operational plan that addresses the communication and networking activities, as well as evaluates the needs for the technology pipeline.
- To communicate the network model and services to stakeholders.
- To provide services using the network resources and processes.

**Figure 28. Network of Northern Ontario Technology Transfer Offices Timeline**

Network of Northern Ontario Technology Transfer Offices	year 1-Q1	year 1-Q2	year 1-Q3	year 1-Q4	Year 2	Year 3	Year 4	Year 5
To create the Network of Northern Ontario Technology Transfer Offices								
To plan the re-organization of local resources:								
To implement the re-organization								
To create an operational plan								
To communicate the network model and services to stakeholders								
To provide services through the network’s resources and processes.								

## 4. Research Park and Incubator Network

*Long-term initiative*

### Summary

Normally, biomedical research spin-offs arise from a promising technology that needs further development prior to generating revenue. This is a critical period where firms need access to a wealth of resources, but are in a high risk position and have very limited funds. This is why most, if not all, biotechnology clusters were developed to provide incubator facilities that offer both rental spaces and professional services to leadership of young ventures in order to help them develop their technologies to the point where they can generate revenue or attract sufficient investment to build their own facilities. The incubator initiative proposes a complete repertoire of services and infrastructure to accompany emerging biomedical companies toward corporate success. There will undoubtedly be a growing need for physical space and professional services as commercial ventures spin-off from research activities in the region and facilities should be available to host entrepreneurs. The Biomedical Research Venture Incubator should be a non-for-profit organization with a Board of Directors comprising of key regional stakeholders. The virtual incubator organization would manage a flexible portfolio of real-estate spread across the region, and provide IT infrastructures and links to professional services. The success of the virtual incubator will depend on the success of the development of the biomedical industry in Northern Ontario and the ability of the incubator management to efficiently forecast the needs and manage its portfolio of real-estate efficiently.

To proposes a complete repertoire of services and infrastructure to accompany emerging biomedical companies toward corporate success.

### Vision

The Biomedical Research Venture Incubator will provide a complete repertoire of services and infrastructure to accompany emerging biomedical companies toward corporate success.

### Mission

The Biomedical Research Venture Incubator is a boundary-less infrastructure that supports emerging companies in the biomedical sector of Northern Ontario, with:

- Physical infrastructures across the region
- IT infrastructures and resources
- Professional services

### The Market Need

Given the strategic direction that the region is pursuing, there will undoubtedly be a growing need for physical space and professional services as commercial ventures spin-off from research activities in the region. However, given the unpredictability in research outcomes and the limited critical mass, it is anticipated that the demand for such facilities will fluctuate significantly. Given the business risk this context represents and notwithstanding that ventures will arise in very different location across

There will undoubtedly be a growing need for physical space and professional services as commercial ventures spin-off from research activities in the region.

Northern Ontario, investment in a fixed dedicated infrastructure may not be advisable. Therefore, a model that is flexible in size and geographic location would be warranted.

## Background

### Objectives

- To provide rental space for biomedical research activities. Such infrastructure would be designed to readily accommodate specialized equipment, and comply with safety, regulatory and environmental requirements for clients' installations.
- To provide its tenants with IT infrastructures such as high speed internet, virtual libraries, etc.
- To offer its tenants or members a gamut of professional services needed for such endeavors to progress toward commercialization (e.g. legal services, intellectual property services, network of investors, industry network, business advices, coaching opportunities, access to mentors, etc.)

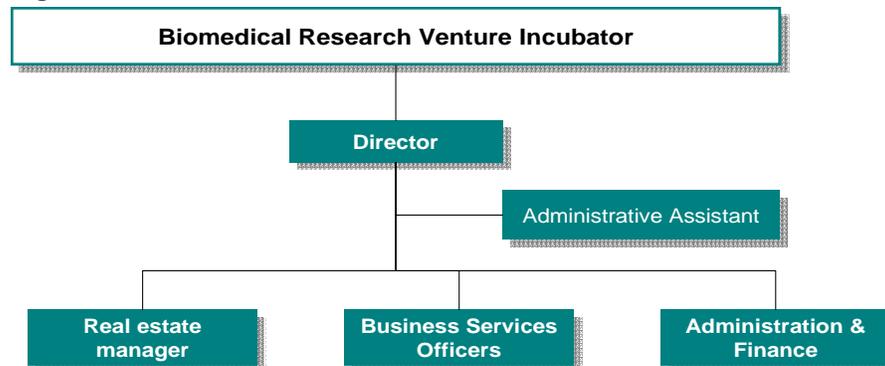
### Strategy

#### Roles and responsibilities

The Biomedical Research Venture Incubator should be a non-for-profit organization with a Board of Directors comprising key regional stakeholders that would have financially contributed to the initiative. Possible contributors include NOSM, Regional Innovation Network (RIN), FedNor, the Northern Ontario Heritage Fund Corporation (NOHFC), municipalities, universities, or others. The organization would be run by an appointed director that should be dedicated to that function and be independent of the participating organizations. A real estate manager will be responsible to build, acquire, or rent the space required for the Incubators' tenants. This person will manage the portfolio of real estate to keep it lean while being readily able to secure space in the appropriate location for new opportunities. The Business Service Officer would be responsible for building a team or for creating partnerships with service providers and be in a position to effectively meet the tenants' needs in terms of professional services, IT infrastructure, and resources.

The Biomedical Research Venture Incubator should be a non-for-profit organization with a Board of Directors comprising key regional stakeholders.

**Figure 29. Biomedical Research Venture Incubator Roles**



### Human resources

Besides the management resources described above, the mission of the Biomedical Research Venture Incubator warrants a number of professionals and technical staff to meet its ambitious goal of being able to accompany its clients along the road to commercialization. However, until a substantial number of tenants are brought in, it would not be efficient to build such a team in-house especially since similar resources are available in the region e.g., the Network of Northern Ontario Technology Transfer Offices. In fact, coordination among the several initiatives proposed in the strategy for growing the Northern Ontario Biomedical sector should be seeking, minimizing duplications, maximizing synergies, and leveraging every asset of the region into a cohesive network.

### Infrastructure, equipment, tools & systems

Because the region's assets are dispersed over a large territory and the critical mass of innovation is relatively limited, Northern Ontario needs an innovative model for incubating young ventures. The model proposed here, is one of a virtual incubator. Incubating a bio-medical spin-off is beyond just providing laboratory space to entrepreneurs; it involves providing access to business advice and professional services, access to a network of investors and industry partners, as well as to infrastructures such as virtual libraries and administrative resources. This initiative was thus proposed to create a virtual incubator organization that would manage a flexible portfolio of real-estate spread across the region, and provide IT infrastructures and links to professional services as well as administrative resources to its members/clients. These services would be available virtually across the Northern Ontario territory.

The detailed needs in terms of physical space will be assessed according to existing and emerging opportunities. Fit-outs and equipments would be the responsibility of the tenants. However, biomedical research activities generally require a subset of research equipment that is generally shared among researchers. Being able to co-localize several tenants would enable them to share some equipment. Alternatively, proximity to universities could allow tenants to access the excess capacity of some specialized equipments for a fee. Also, the incubator may want to consider taking-on the responsibility for some services such as biohazard waste management, chemical wastes management, centralize purchasing, etc., if it were demonstrated that it adds value for the tenants.

### Processes and communications

The Biomedical Research Venture Incubator should be connected to the Network of Northern Ontario Technology Transfer Offices, and this channel would be used to gather potential clients. Furthermore, incubator management should, through its Business Service Officer, build tight links with the different regional stakeholders such as the Northern Ontario Venture Capital Fund, the Regional Innovation Centre, and other private services providers and fund providers. There should also be links with external resources not already linked through other local partners.

A Virtual incubator organization that would manage a flexible portfolio of real-estate spread across the region, and provide IT infrastructures and links to professional services.

## Reward System

By being a non-for-profit organization, the Biomedical Research Venture Incubator directors and management do not benefit from the traditional reward of profit sharing. However, the success of the incubator will provide indirect benefits to its founding organizations in different manners e.g. an organization like FedNor or NOHFC would be rewarded from this initiative success by economic development outcomes; the universities by seeing its innovations on the path to commercialization with the associates' incomes, etc. Nonetheless, the directors of the incubator should also have access to rewards linking to the incubator's performance. This key driver of performance should not be underscored, and the director, managers, and officers of the incubator should have bonuses based on metrics such as:

- Number of tenants
- Fund raised by tenants
- Key milestones met by tenants

## Regional Assets

- The Northwestern Technology Centre already offers incubating space and services. This centre could play different roles in the Biomedical Research Venture Incubator initiative. Such roles could be:
  - Take ownership of this initiative and build it as a division or spin-off.
  - Partner with the Biomedical Research Venture Incubator
  - Serve as a model for the Biomedical Research Venture Incubator
- The Network of Northern Ontario Technology Transfer Offices should be a strategic partner serving two roles: 1) to be the storefront between the incubators and the potential tenants, and 2) to be a service provider for the incubator's tenants.
- The Northern Ontario Venture Capital Fund should be a strategic partner in either supporting financially the tenants, or coaching them about raising funds through them or other financial partners.
- The Regional Innovation Centre as a regional leader in biotechnology innovation in Northern Ontario should provide its assistance when appropriate.

## Financial Strategy

The incubator would require seed funds to create and build the non-profit organization that will manage the incubators. An initial investment in real estate will also be required. This investment should be used along the following scenarios:

- Build or acquire a minimum square footage for forecasted need
- Create a fund to be used for capital investments in physical infrastructures as the demand materializes.

Alternatively, the direction of the Biomedical Research Venture Incubator may choose to leave real estate management to a private partner. However, such a scenario would increase the costs for tenants and should be envisioned in the context where it would be deemed more strategic to build

The incubator would require seed funds to create and build the non-profit organization that will manage the incubators.

new infrastructures, where financial risks are higher and the private sector may be better positioned to mitigate them.

The seed funds could be raised from government agencies and potential private partners. Such agencies may include NOSM, Regional Innovation Network (RIN), FedNor, the Northern Ontario Heritage Fund Corporation (NOHFC), municipalities, universities, industry Canada, or others. Private partners would be real-estate developers. As for the operation of the incubators including service provisions, its fund should be self-sustaining through fee-for-service.

Capital investments in this initiative are expected to be ~\$5M over 5 years. Service provision (excluding service contracted to partners included in this strategic exercise) should amount to ~\$200K/year.

**Risk and Critical Success Factors**

The incubator success is directly linked to two factors:

- The success of the overall strategy for the development of the biomedical industry in Northern Ontario
- The ability of the Biomedical Research Venture Incubator management to efficiently forecast the needs and manage its portfolio of real-estate efficiently

**Steps to Move Forward**

- Create the Biomedical Research Venture Incubator around a solid management team
- Conduct an assessment of the current and emerging needs for incubator space (quantitative and qualitative)
- Conduct a survey of real-estate available and the need and cost for upgrading these available infrastructures to meet tenants' specifications
- Raise funds for capital investments
- Create the channels with partners in service provisions and build teams that will fill the remaining gaps in service provisions.
- Acquire or build infrastructure needed
- Initiate operations

The success of the virtual incubator will depend on the success of the development of the biomedical industry in Northern Ontario and the ability of the incubator management to efficiently forecast the needs and manage its portfolio of real-estate efficiently.

**Figure 30. Biomedical Research Venture Incubator Timeline**

Biomedical Research Venture Incubator	Year 1-Q1	Year 1-Q2	Year 1-Q3	Year 1-Q4	year 2	year 3	year 4	year 5	year 6	year 7	year 8	year 9	year 10
Create the Biomedical Research Venture Incubator													
Assessment of the current and emerging needs													
Survey of real-estate available													
Raise funds for capital investments													
Create the channels with partners													
Acquire or build infrastructure needed													
Initiate operations													

## 5. Liberal, Harmonized Intellectual Property Policies

*Mid term initiative*

### Summary

To achieve any sizable success in commercialization of health research in the region, the varying intellectual property policies of the different institutions across the region will need to be harmonized. Most important of all, they will need to be liberal in the rights accorded to investigators to profit from their discoveries.

This initiative focuses on aligning intellectual property policies across the region so that they are consistent and liberal in nature. Such policies already exist at universities in Northern Ontario, but should extend into the hospitals and other clinical centres where original research will be conducted over the coming years. Despite the current legislative environment for hospitals, this can be done with the right legal structures.

Such policies are a competitive edge in attracting and retaining top researchers from larger centres, because they are able to profit from the commercial applications of their discoveries.

### Vision

The creation of an intellectual property regulatory environment that attracts researchers to Northern Ontario and makes it easy for them to commercialize their research.

### The Market Need

Adopting a harmonized and liberal approach to intellectual property is a critical success factor for commercialization and to attract investment into Northern Ontario for a health research industry.

There are now multiple examples internationally and in Canada that show that health research clusters are more successful and produce more new technology businesses where investigators have major or all rights to the intellectual property they develop. Conversely, institutions that are overly controlling and retain all rights to intellectual property developed by their employees are poor at commercializing their discoveries.

It is important for the success of the grid strategy for investors in new bioscience businesses in the region and for investigators collaborating across the region to have a similar regulatory environment to form “spin out” businesses. If there isn’t similarity, where collaboration has resulted in research with possible commercial applications that has intellectual property owned by more than one institution, the viability of a new venture will be determined by the institution with the most restrictive rules. Thus, one institution which does not allow any intellectual property rights for its staff will cause a number of other institutions to under perform if they collaborate together.

A harmonized and liberal approach to intellectual property is a critical success factor for commercialization.

The term “spin-out” as used above refers to businesses that are formed in the private sector to create and sell commercial products and services based on research that was originally conducted in another environment, typically a university, government or research foundation laboratory, although sometimes the research originates in a large corporation.

With the setting up of a new medical school, this is a golden opportunity for the NOSM/Northern Ontario to distinguish itself and create a competitive advantage by having the most investor-friendly intellectual property policy of any medical school in Canada. Getting this right will enable the region to distinguish itself and actively attract researchers in.

This would achieve two aims. Firstly, this will attract good researchers who see commercial applications for their work and who may move to Northern Ontario from other environments that would be more stifling for entrepreneurial scientists in comparison.

Secondly, it would be more attractive for private sector investment to the region. It helps to overcome barriers such as physical distance from the offices of many venture capital funds by providing a motivating factor.

The interviews that were undertaken with leaders in the health research industry as part of this project identified the importance of taking strong steps to publicly value, promote and implement a technology commercialization focus.

Notwithstanding their industry affiliation, all of the leaders interviewed saw the need in more rural/remote regions for significant effort to be put into the development of an integrated well-networked technology commercialization process. An important component within this was identified as the development of intellectual property policies that provide incentives to inventors and technology management.

The benchmarking exercise of other health science clusters conducted during this project identified as important points for recruiting top scientific researchers to a region:

- provision of excellent compensation packages,
- substantial participation in revenues generated through commercialization of researcher intellectual property, and
- excellent laboratory infrastructure

This is one of the most important components for creating a culture of science commercialization in a region.

## Background

### *Objectives*

Liberal institutional intellectual property policies, particularly at the medical school, the two universities and the main hospitals allow researchers a substantial share of revenues generated through commercialization of intellectual property developed by them.

Forging a strong and intellectual property policy will enable the region to distinguish itself and actively attract researchers.

A strong intellectual property policy is one of the most important components for creating a culture of commercialization.

Policies should be similar enough e.g. harmonized such that all of the key institutions have at least the same principle of substantial proportion of the revenues from commercialization going to the developers of that intellectual property.

## **Strategy**

NOSM can act as a catalyst to get this process initiated as it is uniquely placed in having relationships with two of the main universities and hospitals in Northern Ontario.

### Roles and responsibilities

- **Medical School**  
To act as a catalyst to get this process initiated as it is uniquely placed in having relationships with two of the universities and main hospitals.
- **Universities**  
To input into the process to align intellectual property policy within the region and to alter policy where necessary to be as favourable as possible for researchers.
- **Hospitals and clinical centres**  
To input into the process and work within the current legal framework to alter intellectual property policy to be as favourable as possible for researchers.

### Human resources

Project manager (part-time) to co-ordinate and drive the timetable of the process. This person could be located at the medical school or at any one of the participating institutions. The most likely scenario would be at either the medical school, Laurentian or Lakehead University.

Beyond this, the remainder of the Human Resources needs are management time at those institutions making changes to their intellectual property policies.

During the initial phase of this initiative, one to two consultants will be needed to facilitate the initial sessions and create a work plan.

Legal counsel with specific healthcare experience will need to be consulted during the policy changes, particularly for the hospitals, so that the correct structures are put in place to comply with the laws of Ontario.

### Processes and communications

A coordinating project manager will monitor progress, drive the process of aligning policy according to an agreed work plan and collate documentation. Frequent communication, particularly with the hospitals, will be needed. Best practices from within and outside Northern Ontario will need to be communicated to the participants as well.

The convening of meetings should make as much use as possible of technology to minimize travel time and expense. The videoconferencing capabilities of the two medical school campuses at Sudbury and Thunder Bay should be used to reduce travel.

## Reward System

Ideally, there should be some form of performance bonus payment possible to executive managers of the institutions who would have the change to intellectual property policy as part of their personal management objectives for the year.

However, depending on the type of employment contracts that are in place for such executives, this may or may not be possible in all cases.

Other reward approaches can be taken such as retreats for those who are working on intellectual property policy changes at a congenial venue, which would allow for recreation as well as for informal discussion, idea sharing and team formation as people get to know one another better.

The overall reward for the institutions is greater attraction of research to the region, which attracts funding, upgrades facilities and is stimulating for its participants.

## Regional Assets

The current stakeholders are the relevant institutions that usually produce intellectual property relevant for a health sciences cluster. These are the universities in the region, such as Lakehead, Laurentian and Nipissing, the medical school, the hospitals and clinical centres at which original research is being undertaken and, potentially, community colleges. At this time, key players at the universities would be the technology transfer offices. Important players at the hospitals would be the hospital CEOs and directors/business development officers of the cancer centres.

The medical school is the best candidate to take a lead role in initiating discussions to start this process because of its unique position at the nexus of two universities and the major hospitals in the region.

A detailed review of the current intellectual property policies would need to be undertaken early on in this process. However, this work has indicated that the universities in the region have more researcher-friendly intellectual property policies than the hospitals and would be good advocates for the advantages of these.

The hospitals' role would be as participants and change agents to put in place necessary corporate structures and policies to allow for researchers to benefit from commercialization. Hospitals typically have policies dictated by legislation that they own all intellectual property developed there. However, it is possible to put in place structures to allow different policies. SHI Consulting works with a leading Canadian law firm which has assisted numerous hospitals in Ontario to do this.

## Resources Needed

As this initiative is about policy change and development to create the right environment for health science businesses to develop, its resource requirements are primarily people's time, including the purchase of some specialist professional advice: legal and consulting. No additional physical resources are needed.

Ideally, executive managers would have the change to intellectual property policy as part of their personal management objectives.

Resource requirements are primarily people's time.

Endorsement of this initiative will be needed at the executive level of management and leadership, but detailed work can be delegated below the hospital CEO and University President/Vice-President level to provide adequate human resources to participate in this key change.

Once the right policies are in place, there should be no ongoing costs.

Some external advice will also be needed. Initially, it would be advisable to use a consultant to bring the stakeholders together, facilitate the creation of the working group from the different institutions and to develop the work plan that will need to be undertaken for this initiative.

Over a two year period, full realization of this initiative would require funds in the range \$250K to \$350K. The approximate breakdown of this expenditure is:

- Consulting: \$60k
- Legal advice and structuring: \$150k to \$250k
- Travel: \$50k

Once the right policies are in place, there should be no ongoing costs or resource needs.

### Financial Strategy

Initial seed money to start off this budget should come from institutions that will participate in research and that understand the advantages of more liberal, aligned intellectual property policies for the health sector in the region. Ultimately, this process will generate returns for the institutions by making it much easier to commercialize research findings.

The proportion that the different institutions have to contribute could be a percentage of their research budget. They can build it in as part of their research overhead when applying for grants. Some of their contribution could be in kind (for example, people's time to a certain value who manage intellectual property at the institution or advise the institution on intellectual property (e.g. intellectual property lawyers who may contribute to this in they feel a particular institution is or could be an important client for them).

This process will generate returns for the institutions by making it much easier to commercialize research findings.

Also, it would be worth approaching the local Northern offices of non-profit organizations such as the Alzheimer's and Stroke foundations to contribute to this initiative. It would contribute to increased research in these areas in Northern Ontario. Currently some of these foundations raise as much as \$40,000 per year in Northern Ontario and end up having to export this money out of the region because they cannot find research initiatives to spend it on with in the region.

Include a training program relating to optimal intellectual property management and best practices for participating institutions and bring in outside speakers. This would contribute knowledge to the process and, at the same time, make it more easily fundable.

If there is still a funding gap, FedNor or NOHFC could be approached to contribute as it would be a matched funding process rather than carrying 100% of the load. This is an important component to have in place for commercialization of health science discoveries in Northern Ontario and a strong case can be made for its funding.

There is a program from NSERC, CHIR and SSHRC called the Intellectual Property Mobilization (IPM) Program<sup>29</sup> which funds (on a matched funding basis) exactly this kind of work. Unfortunately, the competition for this closed on March 1, 2005. However, this will be run again in 2008 and could be applied to if it does not prove possible to raise funding for this as suggested above in the interim.

### Steps to Move Forward

1. Engage consultants to:
  - a. Act as facilitators
  - b. Bring different institutional management teams together
  - c. Conduct stakeholder consultations and facilitated sessions to obtain detailed information on the current policies of the hospitals and clinical centres
  - d. Develop the work plan for the next 2 years to make Northern Ontario's health science research Intellectual Property environment the most competitive in Canada
2. Apply and raise funding for the implementation of the work plan
3. Appoint part-time project manager, probably based at the medical school. This could be a contracted consultant if desired.
4. Implement work plan
5. Rework and write policy in alignment with legislation requirements
6. Create necessary legal structures to allow inventors to benefit from commercialization of their intellectual property

### Critical Success Factors

Critical factors to ensure the success of this endeavour include:

- High-level endorsement for the importance of this initiative e.g. Medical School Dean and Associate Dean, Hospital CEOs, University Presidents and Vice-Presidents of Research
- Participation by the major hospitals and clinical centres
- The existence of a. This is likely to be at the medical school, but as this initiative evolves a champion for it may well emerge at one of the hospitals or cancer centres in Sudbury or Thunder Bay
- Obtaining funding to make necessary changes in policy.

### Risks

Risks to the success of this initiative are principally failure of some or all of the above critical success factors:

- A lack of high-level endorsement for the importance of this initiative at regional hospitals, universities or the medical school. Without this support and emphasis on its importance, other people in the relevant organizations will not buy into it and spend the necessary time to make this happen.
- The major hospitals and clinical centres do not see this initiative as important and do not participate, so that the changes in policy do not come about.

High-level management endorsement for the importance of this initiative will be critical for its success.

<sup>29</sup> [http://www.nserc.ca/professors\\_e.asp?nav=profnav&lbi=b6](http://www.nserc.ca/professors_e.asp?nav=profnav&lbi=b6).

- Failure to engage sufficient stakeholders. Successful engagement will be largely dependent on the high-level management support mentioned above.
- No central point of co-ordination for the initiative.
- No organization wishes to be a true champion for this initiative.
- No resources can be allocated to this effort at participating institutions. These resources are primarily people’s time.
- No funding can be raised to pay for:
  - external advice such as facilitation and work planning at the start of the process
  - legal advice to change policy in alignment with legislation
  - where necessary, to establish appropriate corporate structures
  - travel for meetings

**Milestones and Timelines**

**Figure 31. Liberal, Harmonized Intellectual Property Policies Timeline**

Liberal, Harmonized Intellectual Property Policies	Year 1-Q4	Year 2-Q1	Year 2-Q2	Year 2-Q3	Year 2-Q4	Year 3
Engage consultants as facilitators	█					
Bring institutional management together		█				
Stakeholder consultations		█				
Develop work plan		█				
Raise funding			█	█		
Appoint project manager					█	
Initiate work plan					█	
Rework and write policies						█
Create necessary legal structures						█

## **Conclusion**

NOSM has brought together many regional stakeholders in order to develop three strategies that would drive the health research innovation economy for Northern Ontario. These three strategies, clinical health research, basic health research, and commercialization of technologies arising out of this research, are not intended to be prioritized. Rather, the strategies are interwoven and are intended to be mutually supportive. They have been brought forward to highlight specific opportunities available to various groups now and in the foreseeable future in light of the current global life sciences landscape. In addition, the report highlights specific operational plans to support these opportunities with the objective of promoting regional innovation and economic prosperity through collaboration and partnership. This is accomplished by creating a fertile environment which will attract and retain highly qualified personnel, increase regional and international partnerships, and provide resources to further develop new technology. This report highlights the importance of these partnerships to create a critical mass of expertise and resources in the Northern Ontario region, externally validate ongoing research and provide an innovation culture. It is envisioned that implementation of these strategies and operational plans will create long-term sustainable growth in a global competitive environment.