AGREEMENT RE: FRAUNHOFER PROJECT CENTRE FOR BIOMEDICAL ENGINEERING AND ADVANCED MANUFACTURING AT MCMASTER UNIVERSITY

THIS AGREEMENT RE: FRAUNHOFER PROJECT CENTRE FOR BIOMEDICAL ENGINEERING AND ADVANCED MANUFACTURING AT MCMASTER UNIVERSITY (the "**Agreement**") **IS MADE AS OF THE ____DAY OF _____, 2014** (the "**Effective Date**")

Between:

CITY OF HAMILTON (the "**City**")

-and-

MCMASTER UNIVERSITY (the "**University**")

1. **WHEREAS** The University and Fraunhofer-Gessellschaft zur Forderung der angewandten Forschung e V. ("**Fraunhofer**") entered into the Fraunhofer Agreement (defined below) dated June 18, 2013, by which they agreed to form a research and development unit for new technologies for cell therapy and point-of-care diagnostics research called the Fraunhofer McMaster Project Centre ("**FMPC**") which will be an integral part of the new Biomedical Engineering and Advanced Manufacturing ("**BEAM**") hub at the University;

2. **AND WHEREAS** Fraunhofer is a non-profit German research organization founded in 1949 for the purposes of undertaking applied research to support economic development for the wider benefit of society with an annual research budget of approximately 2 billion Euros (and approximately 23,000 employees). Fraunhofer maintains affiliated research centers in Europe, Asia and the United States;

3. **AND WHEREAS** Fraunhofer's 2012 audited financial statements reflect its non-profit operations and that all income from operations is allocated to its capital, including the capital of its foundation;

4. **AND WHEREAS** the University and Fraunhofer will enter into a joint initiative, but not a legal partnership, by which a research institute of Fraunhofer, called the Fraunhofer Institute for Cell Therapy and Immunology IZI ("**Fraunhofer IZI**") and the University will form and manage FMPC;

5. **AND WHEREAS** FMPC will be a research institute created within the University and will not be a legal entity;

6. **AND WHEREAS** Fraunhofer is a non-profit society for the advancement of applied organized pursuant to the laws of Germany and Fraunhofer IZI is one of 67 research institutes created by Fraunhofer to carry out its objectives. Fraunhofer IZI is an unincorporated division of Fraunhofer and does not have any independent legal status;

7. **AND WHEREAS** the University shall be legally responsible for the financial administration of FMPC and is responsible for administration of all contractual and financial transactions of FMPC and the bank accounts through which those transactions will be conducted;

8. **AND WHEREAS** the University is responsible for the terms and conditions for provision of contract research by FMPC to third parties and utilization of FMPC facilities which terms will be consistent with the University's institutional policies for contract research and facilities use ("**third party contracts**");

9. **AND WHEREAS** the University shall be the legal entity which will enter into all contracts on behalf of FMPC including but not limited to all contracts for the provision of contract research by FMPC;

10. **AND WHEREAS** FMPC's operations will be located at the McMaster Innovation Park, which has a street address of 270 Longwood Road South, Hamilton, Ontario, and which was established by the City and the University ("**MIP**");

11. **AND WHEREAS** MIP is a trust in which the University is the sole beneficiary;

12. **AND WHEREAS** FMPC will be supervised and managed by two directors, one appointed from each of the University and Fraunhofer IZI, each for a five year term. Each director will be supported by an assistant director. The University and Fraunhofer IZI will each appoint one assistant director. The directors and assistant directors shall be supervised by a supervisory board ("**Supervisory Board**"). The Supervisory Board shall be comprised of eight members, four appointed by each of the University and Fraunhofer IZI;

13. **AND WHEREAS** once operational, FMPC will be a center for applied research and development in life sciences and biotechnology with special emphasis on advanced procedures for manufacturing cells, as well as products comprising patient-specific and functionalized (stem) cell preparations, biomolecules, biologicals, devices and support structures for bioanalytics, clinical diagnosis and therapy;

14. **AND WHEREAS** the Business Plan (defined below) has been approved by McMaster, Fraunhofer and Fraunhofer IZI, is attached to this Agreement as Schedule "A", and acknowledges the importance of both the scientific expertise to be gathered at FMPC and the provision of equipment, to make and test automated and scalable processes for Good Manufacturing Practice ("**GMP**") manufacturing of autologous cell therapies and point-of-care diagnostics in order to validate the results of said research for industrial implementation;

15. **AND WHEREAS** the Business Plan indicates that the development of FMPC will capitalize on the strength of both the University and Fraunhofer IZI in developing innovative biotechnologies. Fraunhofer IZI offers significant experience in cell therapy development and GMP cell production. In these fields, medical and economic demands have started to cause an urgent need to increase output quantity, quality and speed. At the same time, cell therapies are envisioned to move beyond the current state of the art by providing tailored genetic **solutions**, e.g. patient- and disease-specific (stem) cell preparations and

by utilizing of bioengineering techniques to enhance cell treatment safety, tracking, applicability, and efficacy;

16. **AND WHEREAS** the Business Plan further provides that part of the intent of FMPC is to develop a new industry around the manufacturing of the instruments, systems management tools and sterile enclosures that will be required by companies around the world to take on the challenge of personalized cell therapies at the most advanced stages. The City's employment and economic base includes the areas of biotechnology, biomedical, medical, health and pharmaceutical, and it wishes to add to and expand its economic diversity in these areas for the purposes of economic development;

17. **AND WHEREAS** the University is responsible for preparation of financial reporting documents for each fiscal year of FMPC, consistent with the Canadian generally accepted accounting principles (the **"FMPC Financial Reporting"**);

18. **AND WHEREAS** all equipment at FMPC will be owned by the University;

19. **AND WHEREAS** all intellectual property created at FMPC will be owned in accordance with the established policies of and agreements between the University and the research funding organization and/or the contract research sponsoring organization, as applicable, including without limitation the IP Policy, as attached in Schedule "G" (the "**IP Policy**").

20. **AND WHEREAS** Fraunhofer has made representations to the City that Fraunhofer operates or participates in other institutes, and such institutes generate economic benefits for the municipalities in which they are located, including, but not limited to: new jobs, new businesses, increased business activity for existing businesses and increased property values assessments;

21. **AND WHEREAS** pursuant to Council direction the City intends to assess the economic benefits of the grants provided by the City to the University under this Agreement through assessment of various indictors, including:

(a) The creation of new full-time, year-round jobs at FMPC, namely 70 – 100 during the Term of this Agreement;

(b) The amount of additional investment in FMPC, including federal and provincial government investment;

(c) The number of businesses, including businesses located in the City of Hamilton and businesses located outside Hamilton, that contract with FMPC for the various services described in the Business Plan;

(d) The number of new businesses that are established in the MIP that are reasonably associated with or involved with, FMPC;

(d) The number of new businesses that are established in the City that are reasonably associated to some degree or involved with FMPC; and,

(e) Increased assessment associated with new business that are established in the MIP or the City and which are reasonably associated or involved with FMPC;

22. **AND WHEREAS** financial contributions to McMaster for FMPC will be provided from three levels of government: municipal, provincial and federal. The City will contribute $4.0 million, Ontario has already provided the $4.0 million to McMaster, and the University will apply to the Government of Canada for a minimum contribution of $8.0 million;

23. **AND WHEREAS** the use of the City's grant of funds will only be for Fit Out Infrastructure Costs as described in section 10.1 of the Business Plan attached hereto as Schedule "A". The building in which FMPC will be located is owned by MIP, and the University through FMPC will be a tenant at the MIP and all of FMPC's equipment will be owned by the University;

24. **AND WHEREAS** the City and the University, after making reasonable due diligence, are of the opinion that: (a) the City is given powers by the *Municipal Act, 2001* (Ontario) for the purpose of providing good government, (b) as part of good government, the City has jurisdiction to promote economic developments, and (c) the Business Plan is consistent with the promotion of economic development within the City;

25. **AND WHEREAS** Pursuant to section 107 (1) of the *Municipal Act, 2001* (Ontario), and despite section 106 of the *Municipal Act, 2001* (Ontario), the City and the University, after making reasonable due diligence, are of the opinion that the City may make a grant for any purpose that it considers to be in the interests of the City, provided such purpose is consistent with its mandate to provide good government;

26. **AND WHEREAS** the City has determined that the grant to the University does not constitute a prohibited provision of assistance, either directly or indirectly, to any manufacturing business or other industrial or commercial enterprise, contrary to section 106 of the Municipal Act, 2001 and that the grant, and this Agreement, do not involve a municipal capital facility within the meaning of section 110 of the *Municipal Act, 2001* (Ontario);

NOW THEREFORE THIS AGREEMENT WITNESSES THAT in consideration of the mutual covenants AND agreements contained herein, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged by the Parties hereto the Parties hereto covenant and agree as follows:

Article 1 Interpretation

1.1 Definitions

In this Agreement unless something in the subject matter or context is inconsistent therewith:

(a) "**Agreement**" means this Agreement entered into between the City and the University and includes all of the schedules listed in section 1.9 and any amending agreement entered into pursuant to section 17.1. The term "this Agreement ", refers to this Agreement in its entirety and not to any particular article, section or other portion of this Agreement and includes any agreement supplemental to this Agreement. Unless otherwise indicated, references in this Agreement to articles, sections or schedules are to articles, sections and schedules of this Agreement;

(b) "**Budget**" means the Budget attached to this Agreement as Schedule "D";

(c) "**Building Code**" means Ontario Regulations 332/12 under the *Building Code Act, 1992* (Ontario);

(d) "**Business Plan**" means the business plan, entitled "Fraunhofer Project Centre BEAM" dated July 30, 2014, attached hereto as Schedule "A" which has been jointly prepared and approved by the University, Fraunhofer IZI and Fraunhofer and which includes but is not limited to a description of:

(1) the management systems, organizational structure and operating plan of FMPC;

(2) the costs required to establish and operate FMPC;

(3) the market analysis supporting the creation of FMPC;

(4) the business opportunities and target customers of FMPC; and

(5) the services that will be offered by FMPC and the benefits to the University, Fraunhofer IZI and Fraunhofer.

Any amendment to the document entitled "Fraunhofer Project Centre BEAM" dated July 30, 2014 will not be deemed to be the Business Plan for purposes of this Agreement (i.e. incorporated into this Agreement), except with the express, written approval of the City. For clarity, the University may amend the document entitled "Fraunhofer Project Centre BEAM" without the approval of the City, but such amendments will only be incorporated into this Agreement if, and as of the time of, the City's express written approval.

(e) "**City's Annual Report**" has the meaning ascribed to it in section 10.1 herein;

(f) "**CM**" means the City Manager for the City and/or his or her designate;

(g) "**Commencement Date**" means the date on which FMPC commences activities and operations at the FMPC Project Centre, as reasonably determined, as communicated in writing, and which shall, in no event, be any later than one (1) year after the Date of Substantial Performance;

(h) "**Date of Substantial Performance**" means the date of substantial performance of the contract relating to the construction and improvements required to create the FMPC Project Centre as identified on a certificate or declaration of substantial performance in the form as required pursuant to the *Construction Lien Act,* R.S.O 1990, c.C.30 and R.R.O. 1990, Reg. 175;

(i) "**Effective Date**" means the date set out at the top of this Agreement, notwithstanding any other date to the contrary;

(j) "**Event of Default**" has the meaning ascribed to in in section 12.1 herein;

(k) "**Failure**" has the meaning ascribed to in section 23.1 herein;

(l) "**Final Schedule of Funding and Expenditures FMPC**" has the meaning ascribed to in section 6.2 herein;

(m) "**FMPC**" has the meaning ascribed to it in Recital 1 herein;

(n) "**FMPC Project Centre**" means the facility at MIP in which FMPC will be located and conduct the majority of its operations and activities;

(o) "**FMPC Semi-Annual Reports**" has the meaning ascribed to it in section 2.1 herein;

(p) "**Force Majeure**" has the meaning ascribed to it in Article 25 herein;

(q) "**Fraunhofer**" has the meaning ascribed to it in Recital 1 herein;

(r) "**Fraunhofer Agreement**" means the agreement between Fraunhofer and McMaster dated June 18, 2013, by which the parties thereto agreed to form a research and development unit for new technologies for cell therapy and point-of-care diagnostics research called the "Fraunhofer Project Centre for Biomedical Engineering and Advanced Manufacturing at McMaster University";

(s) "**Fraunhofer IZI**" means Fraunhofer Institute for Cell Therapy and Immunology IZI;

(t) "**Funds**" means the monies and/or lands that the City provides to the University pursuant to this Agreement in the form of three grants, namely Grant 1 Grant 2 and Grant 3;

(u) "**GM**" means the City's General Manger of Planning and Economic Development and/or his or her
designate;

(v) "**Goals**" has the meaning ascribed to it in section 4.6 herein;

(w) "**Government of Canada**" means Her Majesty the Queen in Right of Canada;

(x) "**Governmental Authority**" means the Government of Canada, any province, territory, municipality, state or any entity exercising executive, legislative, judicial, regulatory or administrative functions of or pertaining to government, or the application, enforcement, or interpretation of Law;

(y) "**Grant 1**" has the meaning ascribed to it in section 4.1 herein;

(z) "**Grant 2**" has the meaning ascribed to it in section 4.1 herein;

(aa) "**Grant 3**" has the meaning ascribed to in section 4.1 herein;

(bb) "**Lands**" has the meaning ascribed to it in section 4.1 herein;

(cc) "**Law**" means all laws (including the common law), by-laws, ordinances, rules, statutes, regulations, treaties, orders, treaties, judgments and decrees, and all official

directives, rules, guidelines, notices, approvals, orders, policies and other requirements of any Governmental Authority whether or not they have force of law;

(dd) "**Material Adverse Effect**" means:

(i) an adverse effect on the operations, properties, assets, condition (financial or otherwise) or prospects of the University, Fraunhofer, Fraunhofer IZI or FMPC;

(ii) an adverse effect on the right, entitlement or ability of the University to perform any of its obligations in this Agreement; or

(iii) an adverse effect on the right, entitlement or ability of the City to exercise or enforce any of its rights, entitlements, benefits or remedies under this Agreement;

(ee) "**MIP**" has the meaning ascribed to it in recital 10 of this Agreement;

(ff) "**New Job**" means either:

(i) a full-time, year-round position of employment at FMPC or MIP that: (A) lasts for a duration of at least one (1) year; and (B) is granted to a person who on the Effective Date was not employed by the University, unless such person was a student of the University on the Effective Date and at the time of commencing employment at FMPC or MIP (as applicable), such person has graduated from the program in which they were enrolled on the Effective Date, or

(ii) a full-time, year-round position of employment, for a duration of at least of one (1) year, created by an employer in the City of Hamilton who conducts business with the FMPC (including employers that have located or relocated to the City of Hamilton as a result of the creation of FMPC).

Positions of employment described in sections 1.1(ff)(i) and (ii) held by the same person for a combined duration of at least one year shall be deemed to be one New Job;

(gg) "**Notice**" means any communication given or required to be given pursuant to this Agreement and in accordance with Article 30 of this Agreement;

(hh) "**Notice Period**" means the period of time determined by the City, in its sole discretion, within which the University is required to remedy an Event of Default, and includes any such period or periods of time by which the City, in its sole discretion, acting reasonably, extends that time.

(ii) "**Ontario**" means Her Majesty in Right of Ontario;

(jj) "**Parties**" means the City and the University;

(kk) "**Party**" means either the City or the University;

(ll) "**Pending Event of Default**" means an event which, but for the requirement of giving notice, a lapse of time, or both, or but for the satisfaction of any other condition subsequent to that event, would constitute an "Event of Default";

(mm) "**Property**" means the property on which MIP is located and which is more particularly described in Schedule "C" attached hereto;

(nn) "**Project**" means the undertaking described in the Business Plan attached to this Agreement as Schedule "A"

(oo) "**Project Improvements**" means the improvements at the Property that will result in the creation of the FMPC Project Centre and for the which the University has been approved for grants totalling $4.0 million from the City, $4.0 million from Ontario, and will apply for a minimum $8.0 million from the Government of Canada and a contribution from the University of $4.0 million and which include the Fit Out Infrastructure Costs and Fit Out –Equipment Costs described in section 10.1 of the Business Plan;

(pp) "**Publicly Funded**" or "**Public Funded**" means the source of funding originates from Government of Canada, any Province of Canada, any municipality in Canada, any Crown Agency as defined in the Crown Agency Act, R.S.O. 1990, c.C.48, any university in Canada, or any agency, corporation or entity controlled, owned or funded by the Government of Canada, any Province of Canada, any municipality in Canada or any university in Canada;

(qq) "**Reports**" means the reports, including Unspecified Reports, described in Schedule "F";

(rr) "**Supervisory Board**" has the meaning ascribed to it in recital 12 herein;

(ss) "Term" has the meaning ascribed to in section 3.1 herein;

(tt) "**Timelines**" means the Project schedule set out in Schedule "E";

(uu) "**University Schedule of Funding and Expenditures FMPC**" has the meaning ascribed to it in section 6.2 herein; and

(vv) "**Use of Funds Report**" has the meaning ascribed to it in section 4.3.2 herein.

1.2 Headings

The division of this Agreement into articles and sections and the insertion of headings are for convenience of reference only and shall not affect the construction or interpretation of this Agreement.

1.3 Number and Gender

Words importing the singular number only shall include the plural and vice versa, words importing the masculine gender shall include the feminine and neuter genders and vice versa.

1.4 Best Knowledge

All provisions contained herein requiring the University to make a determination or assessment of any event or circumstance or other matter shall be deemed to require the University to make all due inquiries and investigations as may be necessary or prudent in the circumstances before making any such determination or assessment.

1.5 Currency

Any reference to dollars or currency shall be to Canadian dollars and currency.

1.6 Schedules

The following are the Schedules annexed hereto and incorporated by reference and deemed to be part hereof:

Schedule "A" – Business Plan

Schedule "B" – Legal Description of Lands

Schedule "C" – Legal Description of Property

Schedule "D"- Budget

Schedule "E" – Timelines

Schedule "F" – Reports

Schedule "G" – IP Policy

1.7 References to City Staff

Any reference to the title of any City employee shall include a reference to any amendment to said title or any successor to the responsibilities associated with said title.

1.8 Statutory References

Any reference in this Agreement to any Law, or to any section of or any definition in any Law, shall be deemed to be a reference to such Law or section or definition as amended, supplemented, substituted, replaced or re-enacted from time to time.

1.92 Recitals

All of the recitals preceding Article 1 of this Agreement are true and correct.

Article 2 Representations, Warranties and Obligations of the University

2.1 Representations, Warranties and Obligations

2.1.1 The University represents and warrants to the City and shall be obligated to perform the following:

(a) it has the full power, authority, legal capacity and power to enter into this Agreement and to perform and meet any and all duties, liabilities and obligations as may be required of it under this Agreement;

(b) it has, and shall continue to have for the Term of this Agreement, the experience and expertise necessary to carry out the Project;

(c) it has taken all necessary actions to authorize the execution of this Agreement;

(d) it has, and shall maintain, in writing, for the period during which this Agreement is in effect:

(i) a code of conduct and ethical responsibilities for all employees at all levels;

(ii) procedures to ensure the ongoing effective functioning of the University and FMPC;

(iii) decision-making mechanisms for itself and FMPC;

(iv) procedures to provide for the prudent and effective management of the Funds;

(v) procedures to enable the successful completion of the Project;

(vi) procedures to enable the timely identification of risks to the completion of the Project and strategies to address the identified risks;

(vii) procedures to enable the preparation and delivery of all Reports required pursuant to section 7.1 of this Agreement; and

(vix) procedures to deal with such other matters as the University considers necessary to ensure that the University carries out its obligations under this Agreement;

(e) the recitals to this Agreement are true and correct to the knowledge of the University, which has performed such reasonable due diligence as necessary to permit it, in good faith, to make this representation and warranty;

(f) the joint initiative with Fraunhofer will be carried out in a manner consistent with the Business Plan;

(g) all revenue, not required to maintain operations of FMPC, will be used to continue programs, research and investment relevant to the continued operation of FMPC for at least 5 years after the later of: (a) Substantive Performance or (b) FMPC commences operations at FMPC Project Centre. After the aforesaid 5 year period the revenue may be used for other research initiatives at the University as well.

(h) As described in section 7.1.2 of the Business Plan the Supervisory Board shall prepare at semi-annual reports ("**FMPC Semi-Annual Reports**") no later than June 15th and November 30th of each year after they commence operations and activities at FMPC

Project Centre, which will provide a comprehensive summary of all activities, a budgetary report as well as a success assessment in relation to preset financial and scientific aims to ensure FMPC success criteria as identified in section 9.5 of the Business Plan will be met and a copy of all FMPC Semi-Annual Reports shall be provided to the City at the same time a copy is provided to the Supervisory Board, and other FMPC Financial Reporting, as may be reasonably requested from the City from time to time.

(i) FMPC will be created pursuant and be subject to the University's applicable policy: Guidelines for the Governance and Review of Research Institutes, Centres and Groups as well as pursuant to the Fraunhofer Guidelines for Establishing and Management of Project Centres;

(j) after the completion of the FMPC Project Centre, FMPC's physical location will be at the MIP;

(k) FMPC's operations, activities and business will commence in a temporary location at the McMaster Immunology Research Centre but will relocate to the FMPC Project Centre by July I 1, 2016 or such other date as mutually agreed to by the City and the University;

(l) No Event of Default has occurred, or appears reasonably likely to occur as of the date of this Agreement;

(m) the University is not a party to any agreement under the terms of which the University is prohibited or restricted from entering into this Agreement or any of the liabilities imposed, or restrictions accepted by the University under this Agreement;

(n) none of the execution or delivery of, the consummation of the transactions contemplated in, or compliance with the terms, conditions and provisions of any of, this Agreement or any of the agreements or documents delivered in connection therewith, by the University, conflicts with or will conflict with, or results or will result in any breach of, or constitutes a default under or contravention of, any Law

(o) this Agreement has been duly executed and delivered and constitutes legal, valid and binding obligations of the University enforceable in accordance with its terms;

(p) all information, representations, statements and declarations (collectively referred to as the "Information") furnished by or on behalf of the University to the City for purposes of, or in connection with, this Agreement is or will be true, accurate and complete in all material respects on the date as of which the Information is given and shall continue to be true, accurate and complete for the Term of this Agreement and not incomplete by omitting to state any material fact necessary to make the Information not misleading at such time in light of then-current circumstances. There is no fact now known to the University which has, had, or could reasonably be expected to have, a Material Adverse Effect; and

(q) there are no actions, suits or proceedings pending or to the knowledge of the University threatened against or adversely affecting the University in any court or before any federal, provincial, municipal or other governmental department, commission, board, bureau or agency, Canadian or foreign, which may have an adverse effect on the completion of the Project or the activities, operations or business of FMPC.

2.2 Supporting Documentation

Upon request, the University shall provide the City with proof of the matters referred to in section 2.1.

2.3 Survival and Repetition of Representations and Warranties

The representations and warranties set out in section 2.1 herein will be deemed to be repeated by the University as of the date of each of advancement of Grant 1, Grant 2 and Grant 3 and shall apply for the entire Term.

Article 3 Term

3.1 Term

The term of this Agreement shall commence on the Effective Date and shall, subject to section 4.1, expire 7 years from the Commencement Date (the "Term").

Article 4 Funds

4.1 Amount

The City shall provide to the University the Funds in accordance with the terms of this Agreement. The provision of Funds is conditional upon Council for the City approving the sale of the lands described in Schedule ``B`` hereto (the "Lands"). The sale of Lands is at the sole discretion of the Council of the City and the Parties agree that this Agreement shall in no manner bind Council's discretion. If Council for the City does not approve the sale of the Lands the University shall not challenge or dispute City Council's decision. In accordance with section 4.2.1(b) below, City Council approval for the sale of the Lands shall be a condition precedent for this Agreement, such that this Agreement shall be deemed never to have been effective. No Funds will be provided to the University unless and after the Lands are conveyed to the University. The Funds will be provided in the form of three grants. The first grant ("**Grant 1**") shall be in the amount of $2,610,694.00, payable from the proceeds from the sale of the Lands. The transfer of the Lands from the City to the University shall be deemed to be at the fair market value of $2,610,694.00 the second grant shall ("Grant 2") be in the amount of $889,306.00. The third grant ("Grant 3") shall be for $500,000.00. The University acknowledges that the City shall not advance any amount greater than the sum of Grant 1 Grant 2 and Grant 3, and any such excess amount granted shall be immediately returned to the City. Grant 1, Grant 2 and Grant 3 shall be deposited into an account designated by the University provided that the account resides at a bone fide Canadian financial institution and is in the name of the University. Both parties acknowledge that they have had an opportunity to appraise the fair market value of the Lands.

4.2 Advance of Funds

4.2.1 Conditions

4.2.1.1 Prior to any advance of any of Grant 1, Grant 2 or Grant 3 by the City to the University, the University shall satisfy all of the following conditions precedent to this Agreement:

(a) Provision to the City by the University of proof satisfactory to the GM that the FMPC Project Centre will be located at MIP; and

(b) Resolution by the Council for the City for the sale of and the University shall purchase the Lands for the purchase price of $2,610,694.00; and

(c) The conveyance of the Lands in accordance with an agreement of purchase and sale approved by Council for the City.

4.2.1.2 In addition to the foregoing conditions in 4.2.1 and notwithstanding anything in this Agreement to the contrary, the following shall be conditions to payments of any of the Funds, and both Parties acknowledge that any delay in the University satisfying any of the following conditions may result in a delay in the payment of Funds:

(a) Provision to the City by the University of such proof or information as the City may request from time to time to satisfy itself that the Project Improvements are proceeding in due course;

(b) Application and reception of all regulatory and building approvals required to commence construction, and sending a copy of same to the City upon request;

(c) Maintenance in good standing by the University of all municipal real property taxes, development charges and any other municipal charges, if any and to the extent applicable;

(d) Compliance by the University with all the terms of this Agreement;

(e) Provision by the University to the City of a copy of the Fraunhofer Agreement); and

(f) the University shall provide the City with proof satisfactory to the GM that: (1) the University has received $4.0 million from Ontario for the creation of the FMPC; and (2) the University has received written approval (namely a Letter of Confirmation or similar document) from the Government of Canada stating that the University will receive a minimum grant of $8.0 million from the Government of Canada for the creation of the FMPC.

4.2.2 Advance of Grant 1

Subject to the University having satisfied the requirements in section 4.2.1 the City shall, 30 days after the closing date of the conveyance of the Lands to the University, advance Grant 1 to the University.

4.2.3 Advance of Grant 2

The City shall advance Grant 2 to the University within five business days of satisfaction of each of the following events:

(i) 45 days after the date of publication of the Certificate of Substantial Performance of the FMPC Project Centre;

(ii) the University has provided proof satisfactory to the GM that Grant 1 has been used by the University exclusively for the purposes described in section 4.3.1 herein;

(iii) the University has provided proof satisfactory to the GM that the University has satisfied all of the requirements of section 4.2.1;

(iv) the University has provided proof satisfactory to the GM that there are no liens, executions or other instruments registered on title to the Property that would adversely affect: the Property, the Project and the financial condition of the University, as determined by the GM in his sole discretion; and

(v) the University has provided proof satisfactory to the =GM there are no actions, suits, executions, liens or proceedings pending or threatened against or affecting the Property that, if successful, would adversely affect the Property, the Project or the financial condition of the University, as determined by the GM in his sole discretion.

4.2.4 Advance of Grant 3

(a) The City shall advance Grant 3 to the University during the Term, after July 1, 2015 and thirty days after the University makes a written request, provided such request: (1) is submitted after July 1, 2015 but at least ninety days prior to the end of the Term, (2) is made to the CM, and (3) contains a report ("**Grant 3 Report**"), satisfactory to the CM in his sole discretion that such Grant 3 Report contains information that the University has fulfilled the following requirements in order for the City to advance Grant 3:

(i) the FMPC is operating substantially in accordance with the Business Plan;

(ii) the University is in compliance with this Agreement;

(iii) within 5 years of the Commencement Date the creation of FMPC has resulted in the creation of no less than 70 New Jobs together with a record of the New Jobs created containing sufficient information to verify that the jobs listed meet the requirements of the definition of New Jobs contained with section 1.1(ff) of this Agreement;

(iv) in addition to the Goal described in section 4.6(a) FMPC has, within 5 years of the Commencement Date, been successful in achieving at least one of the other Goals described in section 4.6(b), (c) and (d) and for greater clarity the foregoing shall exclude the Goal in 4.6(e);

(v) information on the achievement of the Goals as of the date of the report and as is reasonably available to the University;

(vi) the University has satisfied all of the requirements of section 4.2.1;

(vii) Provision to the City of proof satisfactory to the GM that the University has actually received a minimum grant of $8.0 million from the Government of Canada for the creation and operation of FMPC (which shall be in addition to the requirements of section 4.2.1.2(f), and, which, for clarity, may be satisfied by providing such proof in the Grant 3 Report);

(vii) there are no actions, suits, executions, liens or proceedings pending or threatened against or affecting the Property that, if successful, would adversely affect the Property, the Project or the financial condition of the University, as determined by the GM in his sole discretion;

(ix) FMPC is occupying the FMPC Project Centre and is conducting substantially all of its operations, activities and business at the FMPC Project Centre; and

(x) the University has provided to the City a Use of Funds Report pursuant to section 4.3.2 in regards to the use of Grants 1 and 2.

(b) The University shall fulfill all of the requirements set out in section 4.2.4(a) prior to the advance of Grant 3 by the City. If the requirements in section 4.2.4(a) are not fulfilled by the University ninety days prior to the end of the Term the City shall be under no obligation to advance Grant 3.

4.3 Use of Funds

4.3.1 Use of Funds

The City shall provide the Funds to the University for the sole purpose of contributing to FMPC, to be used exclusively by the University for the purpose of: Fit Out Infrastructure Costs, as described in section 10.1 of the Business Plan, for the FMPC Project Centre.

4.3.2 Confirmation of Permitted Use of Funds

Within 30 days after the advance of Grant 2 the University shall provide a report ("**Use of Funds Report**") satisfactory to GM that the Funds have used exclusively for the purposes described in section 4.3.1 herein. If:

(a) the University fails to provide a satisfactory Use of Funds Report within the time period specified herein; or

(b) if the Funds have been used for purposes other than that described in section 4.3.1 herein,

then the provisions of Article 9 apply as if an Event of Default occurred.

4.4 Interest

4.4.1 Interest Bearing Account

If the City advances Funds to the University prior to the University's immediate need for the Funds, the University shall place the Funds in an interest bearing account in the name of the University at a bone fide Canadian financial institution. The University shall from time to time provide in a timely manner an accurate statement of account of the Funds upon request from the City.

4.4.2 Interest

If the University earns any interest on any of the Funds:

(a) the City may deduct an amount equal to the interest from any further advances of Funds; or

(b) the University shall pay an amount equal to the interest to the City as directed by the City.

4.5 Rebates

The University acknowledges that the amount of Funds available to it pursuant to this Agreement is based on the actual costs to the University, less any costs (including taxes) for which the University has received, will receive, or is eligible to receive, a rebate, credit or refund.

4.6 Goals of Funds

The University and the City agree that the City is providing the Funds to the University to accomplish the following economic development goals ("**Goals**") within 5 years from the Commencement Date:

(a) the creation of at least 70 New Jobs;

(b) 5 businesses that have contracted with FMPC (through the University) for the services FMPC provides as described in the Business Plan;

(c) 3 new businesses that are established in Hamilton that are reasonably associated with or involved with FMPC and that were previously not located in Hamilton;

(d) FMPC (through the University) has contracted with at least one or more businesses for the provision of services with a total contract value of $500,000; and

(e) new property assessment in the City reasonably related to the creation of FMPC.

Article 5 Conflict of Interest

5.1 No Conflict of Interest

The University shall carry out the Project and use the Funds without an actual, potential or perceived conflict of interest. The University shall ensure that FMPC conducts its operations without an actual, potential or perceived conflict of interest.

5.2 Conflict of Interest Includes

For the purposes of this Article, a conflict of interest includes without limitation any circumstances where:

(a) the University or FMPC; or

(b) any person who has the capacity to influence the University's or FMPC's decisions, has outside commitments, relationships or financial interests that could, or could be seen to, interfere with the University's or FMPC's objective, unbiased and impartial judgment relating to the Project and the use of the Funds.

5.3 Disclosure to the City of Hamilton

The University shall:

(a) disclose to the City, without delay, any situation that a reasonable person would interpret as either an actual, potential or perceived conflict of interest; and

(b) comply with any terms and conditions that the City may prescribe as a result of the disclosure.

Article 6 Financial Controls

6.1 Adequate Controls

The University shall ensure that there are adequate financial controls in place to ensure the accuracy, completeness and auditability of the University's and FMPC's financial reporting.

6.2 Financial Reporting

The University is responsible for preparation of financial reporting for each fiscal year of FMPC, consistent with generally accepted accounting principles. The University shall on October 31st of each year of the Term provide financial reporting to the City for the prior fiscal year consisting of an audited schedule, prepared consistent with generally accepted accounting principles, in respect of the FMPC, including a statement of income or loss and , actual expenses as reasonably required by the City to determine compliance by the University with its obligations under this Agreement("**University Schedule of Funding and Expenditures FMPC**"). Within 30 days of the expiration of the Term the University shall provide to the City an audited I schedule t, prepared consistent with generally accepted accounting principles, covering the Term of this Agreement in respect of the FMPC, which

shall include a statement of income or loss and actual expenses, as reasonably required by the City to determine compliance by the University with its obligations under this Agreement (**"Final Schedule of Funding and Expenditures FMPC")** Each University Schedule of Funding and Expenditures FMPC and the Final Schedule of Funding and Expenditures FMPC shall be signed by the Chief Financial Officer for the University.

Article 7 Reporting, Records, Accounting and Review

7.1 Reports

The University shall:

(a) submit to the City at the address provided in section 30.1, all Reports in accordance with the timelines and content requirements set out in this Agreement and Schedule "F", or in a form as specified by the City from time to time;

(b) submit to the City at the address provided in section 30.1, any other reports ("**Unspecified Reports**") as may be requested by the City in accordance with the timelines and content requirements specified by the City;

(c) ensure that all Reports and other reports are completed to the satisfaction of the City; and

(d) ensure that all Reports and other reports are signed on behalf of the University by an authorized signing officer.

7.2 Record Maintenance

The University shall keep and maintain:

(a) all financial records (including invoices) relating to the Funds or otherwise to the Project in a manner consistent with generally accepted accounting principles; and

(b) all non-financial documents and records relating to the Funds or otherwise to the Project.

7.3 Inspection

7.3.1 Inspection of Project

For the purpose of ensuring compliance with the terms of this Agreement, the City or its authorized agents or representatives or an independent auditor identified by the City may, at its own expense, upon 24 hours' notice and during regular business hours, enter upon the University's or FMPC's premises to review the progress of the Project and the University's expenditure of the Funds. The University will ensure that its agreement with Fraunhofer contains such provisions so as to ensure that the City has the ability to inspect FMPC's premises in accordance with this section.

7.3.2 Inspection of Records

For the purpose of ensuring compliance with the terms of this Agreement, the City or its authorized agents or representatives or an independent auditor identified by the City may, at its own expense, upon on 24 hours' notice and during regular business hours, enter upon the University's or FMPC's premises, and the University shall cooperate fully, to:

(a) inspect and take extracts from the accounts, records including financial records and invoices, and books and data, whether such aforesaid accounts and records are stored in any format whatsoever including but not limited to paper or electronic format, of the University, Fraunhofer, Fraunhofer IZI and/or FMPC, related to the operation of FMPC; and,

(b) conduct an audit or investigation of the University in respect of the Project and/or the expenditure of the Funds. The City shall provide the results of the audit to the University within a reasonable time of its completion. Any audit performed under this section shall be at the sole expense of the City.

7.3.3 Disclosure

To assist in respect of the rights set out in sections 7.3.1 and 7.3.2, the University shall promptly disclose and provide, without limitation, any information requested by the City, its authorized representatives or an independent auditor identified by the City, and shall do so in a form requested by the City, its authorized representatives or an independent auditor identified by the City, as the case may be.

7.3.4 Fraunhofer Agreement

The Fraunhofer Agreement shall contain each of the following provisions, and shall expressly identify the City as a third party beneficiary to such provisions:

(a) The City or its authorized agents or representatives or an independent auditor identified by the City may, at its own expense, upon 24 hours' notice and during regular business hours, enter upon the FMPC's premises, and Fraunhofer shall cooperate fully, to inspect and take extracts from the accounts, records including financial records and invoices, and books and data, whether such aforesaid accounts and records are stored in any format whatsoever including but not limited to paper or electronic format, of Fraunhofer or FMPC related to the operation of FMPC; and

(b) To assist in respect of the rights set out in this section Fraunhofer shall promptly disclose and provide, without limitation, any information requested by the City, its authorized representatives or an independent auditor identified by the City, and shall do so in a form requested by the City, its authorized representatives or an independent auditor identified by the City, as the case may be.

7.3.7 No Control of Records

No provision of this Agreement shall be construed so as to give the City any control whatsoever over the University's records, except as expressly provided herein.

Article 8 Credit

8.1 Acknowledge Support

Unless otherwise directed by the City, the University shall, in a form approved by the City, acknowledge the support of the City in any publication of any kind, written or oral, relating to the Project.

8.2 Publication

The University shall indicate, in any of its publications, of any kind, written or oral, relating to the Project, that the views expressed in the publication are the views of the University and do not necessarily reflect those of the City.

Article 9 Freedom of Information and Protection of Privacy

9.1 MFFIPPA

The University acknowledges that the City is bound by the *Municipal Freedom of Information and Protection of Privacy Act,* R.S.O. 1990, c.M.56 ("**MFIPPA**") and that any information provided to the City in connection with the Project or otherwise in connection with this Agreement may be subject to disclosure in accordance with MFIPPA.

Article 10 Goals Reporting

10.1 Goals Reporting

The University shall, annually, for 5 years from the Commencement Date on June 15th for each of the 5 years provide a report(**"City's Annual Report")** the City on the Goals, which report shall provide such information on the achievement of the Goals as is reasonably available to FMPC and the University. The City's Annual Report shall be in a form and content satisfactory to the GM. For 5 years after the Commencement Date, the City shall be entitled to make reasonable inquiries for information for analysis of the Goals, beyond that provided in the City's Annual Report, and the University shall be obligated to respond to those reasonable inquiries.

Article 11 Covenants

11.1 Covenants

The Parties agree that all obligations or agreements contained in this Agreement shall be deemed to be covenants.

11.2 Covenants of the University

So long as this Agreement is in effect, and except as otherwise permitted by the prior written consent of the City, the University covenants and agrees that the following shall apply:

(a) the University shall use the Funds advanced to it under this Agreement for lawful purposes and only in accordance with the terms, restrictions and conditions set out in this Agreement;

(b) the University shall carry out the Project in compliance with all Laws;

(c) the University shall use the Funds for Fit Out Infrastructure Costs as described in section 10.1 of the Business Plan and spend the Funds on Fit Out Infrastructure only in accordance with the Budget;

(d) the University shall not make any changes and shall ensure that FMPC does not make any changes to the Project, the Timelines and/or the Budget, without the prior written consent of the City

(e) the University shall comply with the laws of Ontario, the Government of Canada and the municipal by-laws of the City of Hamilton as they relate to FMPC;

(f) the University shall comply with the City's requirement related to specific insurance terms as set out in Article 29;

(g) the University shall pay in full prior to the advance of Grant 1 and remain in good standing throughout the Term, all outstanding real property taxes (or payments in lieu of taxes, as the case may be) and amounts added to the municipal tax roll for the Property, including any additional fees associated therewith and any penalty and interest currently owed by the University on the Effective Date;

(h) the University shall promptly notify the City of any Event of Default or Pending Event of Default;

(i) the University shall notify the City of the Commencement Date within 24 hours of said date by Notice in accordance with this Agreement;

(j) intellectual property created at FMPC will be owned in accordance with the policies of and agreements between the University and the research funding organization and/or the contract research sponsoring organization, as applicable, including without limitation the IP Policy;

(k) the University shall keep and maintain the Property in good repair and in compliance with the provisions of the City's Property Standards By-law;

(l) the University shall provide confirmation to the City it has received a contribution from Government of Canada in the amount of $8.0 million for the creation of FMPC within 2 days upon receipt of said contribution; and,

(m) on or before July 1, 2016, or such other date as mutually agreed to by the City and the University, FMPC will occupy and conduct substantially all of its operations, activities and business at the FMPC Project Centre at MIP.

Article 12 Default and Remedies

12.1 Events of Default

The occurrence of anyone or more of the following events (each an "**Event of Default**") shall constitute a default under this Agreement:

(a) the City is of the opinion, as determined by the CM, that the University has breached any representation, warranty, covenant or other term of this Agreement,; such breaches include but are not limited to:

(i) failing to carry out the Project in accordance with the terms and conditions of this Agreement;

(ii) failure to use or spend Funds in accordance with the terms and conditions of this Agreement;

(iii) failure to provide, Reports in accordance with the terms and conditions of this Agreement or such other reports as may have been requested pursuant to section 7.1; or,

(iv) failure to comply with requirements of section 7.2 and 7.3;

(b) the University makes an assignment, proposal, compromise, or arrangement for the benefit of creditors, or is petitioned into bankruptcy, or files for the appointment of a receiver;

(c) an event of Force Majeure that continues for a period of 90 days or more.

(d) The sale or the removal from the MIP of a substantial portion of the equipment or other assets used by FMPC; or

(e) a complete or partial cessation of the operations, activities or business of FMPC such that FMPC could no longer reasonably be considered to be operating;

(f) A complete or partial cessation the operations, activities or business of the University such that it could no longer reasonably be considered to be operating;

(g) Grant 1 was not used exclusively for the purposes described in section 4.3.1;

(h) Grant 2 was not used exclusively for the purposes described in section 4.3.1;

(i) Grant 3 was not used exclusively for the purposes described in section 4.3.1;

(j) Failure to comply with section 4.3.2 in regards to both the timing of the provision of the proof and the use of the Funds;

(k) the relocation of any FMPC facilities at MIP to a property other than MIP;

(l) the Project Improvements have not been completed in accordance with the Ontario Building Code;

(m) Ontario does not provide or the University returns the monies or a portion thereof, provided by the Ontario in respect of FMPC pursuant to the agreement between Ontario and the University dated March 28, 2014;

(n) the Government of Canada has not provided, 90 days prior to the end of the Term a minimum of $8.0 million to the University for the creation or operation of FMPC

(o) the University returns the monies or a portion thereof, provided by the Government of Canada for the creation or operation of FMPC;

(p) any representation or warranty of the University contained in this Agreement is incorrect in any material way; or

(q) FMPC has not occupied the FMPC Project Centre and did not commence to conduct substantially all of its operations, activities and business at the FMPC Project Centre prior to or on July 1, 2016 and the City and the University have not mutually agreed to an alternative date to July 1, 2016 within 30 days from July 1, 2016.

12.2 Remedies

In the event of the happening of one or more of the Events of Default, the City, may at its sole discretion at any time, take one or more of the following actions:

(a) cancel any further advances of any Funds under this Agreement;

(b) provide the University with an opportunity to remedy the Event of Default;

(c) suspend the advance of any Funds or portion thereof for such period as the City in its sole discretion, determines appropriate;

(d) reduce the amount of the Funds;

(e) demand the repayment of any of the Funds advanced to the University by the City;

(f) demand the repayment of an amount equal to any Funds the University used, but did not use in accordance with this Agreement;

(g) terminate this Agreement at any time, including immediately, upon giving Notice to the University.

12.3 No Prejudice

For greater certainty, it is expressly understood and agreed that the rights and remedies of the City under this Agreement or under any other document are cumulative and are in addition to, and not in substitution for, any rights or remedies provided by Law or by equity; and any single or partial exercise by the City of any right or remedy for a default or breach of any term, covenant, condition or agreement contained in this Agreement shall not be

deemed to be a waiver of or to alter, affect or prejudice any other right or remedy or other rights or remedies to which the City may be lawfully entitled under this Agreement or otherwise for such default or breach. For greater clarity, if an Event of Default occurs the University acknowledges that the City is not obligated to provide the University with an opportunity to remedy the Event of Default and the City can exercise any one or more of the other actions described in section 12.2 herein.

12.4 Opportunity to Remedy

If, in accordance with section 12.2(b), the City provides the University with an opportunity to remedy the Event of Default, the City shall provide Notice to the University of:

(a) the particulars of the Event of Default; and

(b) the Notice Period.

12.5 Repayment

12.5.1 Debt Due Immediately

The Funds shall be repaid, in whole or in part (as applicable), immediately to the City by the University if:

a) the City demands the repayment of any Funds pursuant to sections 12.2(e) and (f) or otherwise under this Agreement, from the University; or

b) the University owes any Funds or any other money to the City, whether or not their return or repayment has been demanded by the City,

such Funds or other money shall be deemed to be a debt due and owing to the City by the University, and all Funds and monies owing shall immediately become due and payable upon demand all without notice, presentment, protest, demand, notice of dishonour or any other demand or notice whatsoever, all of which are hereby expressly waived by the University. All indebtedness and liability of the University to the City that becomes payable on demand in accordance with the terms herein, is repayable by the University to the City at any time on demand. Without limiting any of its covenants and obligations set out elsewhere in this Agreement, the University agrees to pay all costs and expenses in connection with all out-of-pocket costs and expenses (including without limitation reasonable legal, expert and consulting fees) of the City in connection with enforcing the rights of the City under this Agreement.

12.5.2 Interest Rate

The City may at its sole discretion charge the University interest on any money owing by the University at a variable rate per annum equivalent to the highest rate charged by the City from time to time in respect of property tax arrears calculated and payable monthly. Interest shall apply to the date of the actual advance of the Funds.

12.5.3 Payment of Money to City

The University shall pay any money owing to the City by cheque payable to City of Hamilton and mailed to the City at the address provided in section 30.1.

Article 13 Indemnification

13.1 Indemnification

In addition to any liability of the University to the City under any other provision of this Agreement , the University covenants to indemnify and hold harmless the City and its officers, employees and representatives from and against any and all liabilities, loss , costs, damages, expenses (including legal, expert and consultant fees), causes of action, actions, claims, proceedings, and obligations of any kind that may be sustained incurred, brought, prosecuted or asserted against, any of them by any third party, including any Governmental Authority, in any way arising out of or in connection with this Agreement or in connection with the Project or in connection the operations of FMPC. For the purposes hereof, matters arising from the operation of FMPC shall extend to any matter, directly or indirectly relating to FMPC, including, without limitation, injuries suffered by any person while using the facilities of FMPC, including the equipment therein, damage to property, and claims arising from the act or omission of any employee, contractor or agent of FMPC, the University, Fraunhofer or Fraunhofer IZI.

Article 14 Change of Circumstances

14.1 Change of Circumstances

If, after the date of this Agreement , the adoption of or change to any Law, or any change in the interpretation or application thereof by any court or by any Governmental Authority, now or hereafter makes it unlawful or impossible for the City to make an advance of Funds under this Agreement , or makes any advance of Funds already made unlawful, the City may, by written notice to the University, declare its obligations under this Agreement to be terminated, whereupon the same shall forthwith terminate, and the University shall pay within the time required by such Law any advances of Funds made. If any such change shall only affect a portion of the City's obligations under this Agreement which is, in the opinion of the City and the City's Counsel in their sole discretion, acting reasonably, severable from the remainder of this Agreement, so that the remainder of this Agreement may be continued in full force and effect without otherwise affecting any of the obligations of the City or the University under this Agreement , the City shall solely declare its obligations under that portion so terminated.

Article 15 No Relationship

15.1 No Relationship

No partnership is created by this Agreement. Nothing contained in this Agreement shall or shall be deemed to constitute the City and the University partners, agents, joint venturers,

employees or any other relationship whereby either could be held liable for any act or omission of the other. The University shall not take any actions that could imply one of the foregoing relationships. Neither the City nor the University shall have any authority to act for the other or incur any obligation or responsibility on behalf of the other.

Article 16 Survival

16.1 Survival

The provisions in Article 1, any other applicable definitions, sections 4.4.2(b), , 6.2(to the extent that the University has not provided any of the University Schedule of Funding and Expenditures FMPC and/or the Final Schedule of Funding and Expenditures FMPC), 7.1 (to the extent that the University has not provided the Reports or other reports as may be requested by the City to the satisfaction of the City), 7.2, 7.3, Articles 8, and 10(to the extent that the University has not provided any of the City's Annual Reports and/or has not fully responded to any reasonable inquiry from the City for information for analysis of the Goals) , sections , 12.1 (a), (b), (c), (f), (g), (h), (i), (j), (k), (l), (m), (n), (o) and (p), 12.2, (e), (f) 12.3, 12.5, Article 13, section 14.1, Articles 16, 17, 19, 20, 27, section 28.2, Articles 30 and , 31 and all applicable cross-referenced provisions and schedules shall continue in full force and effect for a period of 2 years from the date of expiry or termination of this Agreement.

Article 17 Entire Agreement

17.1 Entire Agreement

This Agreement, including all attachments, contains the entire agreement and understanding between the Parties and supersedes all prior and contemporaneous oral or written agreements and representations between the Parties. Any amendments shall be in writing and signed by all Parties.

Article 18 Successors and Assigns

18.1 Successors and Assigns

This Agreement and shall be binding upon and enure to the benefit of the City, the University and its successors and assigns, except that the University shall not assign any rights or obligations with respect to this Agreement without the prior written consent of the City and the City's consent maybe arbitrarily withheld. The University shall not dispute the City withholding any consent to assign this Agreement.

Article 19 Governing Law

19.1 Governing Law

This Agreement shall be governed by and construed in accordance with the laws of the Ontario. Any actions or proceedings arising in connection with this Agreement shall be conducted in Ontario.

Article 20 Severability

20.1 Severability

The invalidity or unenforceability of any provision of this Agreement shall not affect the validity or enforceability of any other provision of this Agreement. Any invalid or unenforceable provision shall be deemed to be severed.

Article 21 Further Assurances

21.1 Further Assurances

The University shall do or cause to be done all acts or things necessary to implement and carry into effect the terms and conditions of this Agreement to their full extent.

Article 22 Counterparts

22.1 Counterparts

This Agreement may be executed in any number of counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

Article 23 Other Agreements

23.1 Other Agreements

If the University:

(a) has failed to comply (a "**Failure**") with any term, condition or obligation under any other agreement with the City;

(b) has been provided with notice of such Failure in accordance with the requirements of such other agreement;

(c) has, if applicable, failed to rectify such Failure in accordance with the requirements of such other agreement; and

(d) such Failure is continuing,

the City may suspend the payment of Funds for such period as the City in its sole discretion determines appropriate.

Article 24 Waiver

24.1 Waiver

If a Party fails to comply with any term of this Agreement, that Party may only rely on a waiver of the other Party if the other Party has provided a written waiver in accordance with the Notice provisions in Article 30. Any waiver must refer to a specific failure to comply and shall not have the effect of waiving any subsequent failures to comply.

Article 25

Circumstances Beyond the Control of Either Party

25.1 Meaning of Force Majeure

Subject to section 25.3, Force Majeure means an event that:

(a) is beyond the reasonable control of a Party; and

(b) makes a Party's performance of its obligations under this Agreement impossible, or so impracticable as reasonably to be considered impossible in the circumstances.

25.2 Force Majeure Includes

Force Majeure includes:

(a) infectious diseases, war, riots and civil disorder;

(b) storm, flood, earthquake and other severely adverse weather conditions;

(c) lawful act by a public authority; and,

(d) strikes, lockouts and other labour actions,

if such events meet the test set out in section 25.1.

25.3 Force Majeure Shall Not Include

Force Majeure shall not include:

(a) any event that is caused by the negligence or intentional action of a Party or such Party's agents or employees; or

(b) any event that a diligent Party could reasonably have been expected to:

(i) take into account at the time of the execution of this Agreement; and

(ii) avoid or overcome in the carrying out of its obligations under this Agreement.

25.4 Failure to Fulfill Obligations

Subject to section 12.1(c), the failure of either Party to fulfil any of its obligations under this Agreement shall not be considered to be a breach of, or Event of Default under, this Agreement to the extent that such failure to fulfill the obligation arose from an event of Force Majeure, if the Party affected by such an event has taken all reasonable precautions, due care and reasonable alternative measures, all with the objective of carrying out the terms and conditions of this Agreement.

Article 26 Consent by City

26.1 Consent

The City may impose any terms and/or conditions on any consent the City may grant pursuant to this Agreement.

Article 27 Funds Not Spent

27.1 Funds Not Spent

Upon the and without limiting any rights of the City under Article 12, if the University has not spent all of the Funds advanced by the City under this Agreement as provided for in the Budget the University, the unspent Funds shall form a debt to the City and the University shall return to the City the unspent portion of the Funds to the City forthwith as if the City had made a demand for payment of said monies.

Article 28

Acquisition of Goods and Services and Disposal of Assets

28.1 Acquisition

If the University or FMPC acquires supplies, equipment or services with the Funds, it shall do so through a process that promotes the best value for money.

28.2 Disposal

The University shall not and shall ensure FMPC shall not, without the City's prior written consent, sell, lease or otherwise dispose of any asset purchased with the Funds or for which Funds were provided, the cost of which exceeded $50,000 at the time of purchase.

Article 29 Insurance

29.1 Property Insurance

The University shall obtain and maintain property all risks insurance to insure the FMPC Project Centre and its contents, on a replacement cost basis with limits equal to the value of the FMPC Project Centre and its contents. The City shall be named as a loss payee as their interest may appear. The University shall provide a certificate of Insurance to the City prior to any advance of Funds being made in accordance with section 4.2 and thereafter, throughout the Term of this Agreement, the University shall provide a certificate of insurance no later than 20 days prior to the renewal date of the policy. The certificate shall provide that at least 30 days prior written notice shall be given to the City by the insurer before the insurer or University takes any steps to cancel, terminate, fail to renew, amend or otherwise change or modify the insurance or any part thereof. The certificate holder shall be addressed as the City of Hamilton, Attention: City Clerk, 71 Main St. West, 7th Floor, Hamilton, Ontario

29.2 Mandatory Repayment from Proceeds of Insurance

If, during the Term of this Agreement, the University or FMPC receives any proceeds of insurance then an amount equal to the entire net amount of those proceeds which is not applied to the repair or replacement of the FMPC Project Centre Property and its contents, within ninety (90) days of receipt of any such amount shall be paid by or on behalf of the University to the City forthwith. Any amount paid to the City pursuant to this section 29.2 shall not exceed the total sum of Funds advanced by the City to the University.

29.3 Commercial General Liability Insurance

The Recipient represents and warrants that it has, and shall maintain for the Term of the Agreement, at its own cost and expense, with insurers having a secure A.M. Best rating of B+ or greater, or the equivalent, all the necessary and appropriate insurance that a prudent person carrying out a project similar to the Project would maintain, including commercial general liability insurance on an occurrence basis for third party bodily injury, personal injury and property damage, to an inclusive limit of not less than two million dollars ($2,000,000) per occurrence. The policy shall include the following:

(a) the City of Hamilton as additional insured with respect to liability arising in the course of performance of the Recipient's obligations under, or otherwise in connection with, the Agreement;

(b) a cross-liability clause;

(c) contractual liability coverage; and

(d) a 30 day written notice of cancellation, termination or material change.

29.4 Proof of Insurance

The Recipient shall deposit with the City a certificate of insurance prior to commencing the Project Improvements. Certificate Holder will be addressed as the City Of Hamilton, City Hall, 71 Main Street West, Hamilton, Ontario L8P 4Y5 attn: Planning and Economic Development. All certificates, cancellation, nonrenewal or adverse change notices should be mailed to this address.

Article 30 Notice

30.1 Notice

All notices or other communications under this Agreement shall be given in writing by personal delivery or postage prepaid registered mail addressed to the City and University respectively as set out below:

in the case of the City to:

City of Hamilton

Planning and Economic Development Department

71 Main Street West, 1st Floor

Hamilton, Ontario

L8P 4Y5

Attention: General Manager, Planning and Economic Development

And with a copy to:

City of Hamilton

City Manager's Office, Office of the City Clerk

Finance and Corporate Services Department

71 Main Street West, 1st Floor

Hamilton, Ontario

L8P 4Y5

Attention: City Clerk

in the case of the University to:

McMaster University

1280 Main St. West, Hamilton,

Ontario L8S 4L8

Attention: Vice President, Research and International Affairs

30.2 Notice Given

Notice shall be deemed to have been given and received on the day on which the other Party receives the Notice except that if notice is provided by the University on a day that the City Hall for the City is closed to the public notice shall be deemed to have been given and received on the next day that the City Hall is open to the public.

Article 31 No Party Deemed Drafter

31. No Party Deemed Drafter

If it is necessary for an arbitrator or a court to interpret any provision of this Agreement, neither Party to this Agreement shall be considered the drafter of it and therefore neither Party shall have this Agreement construed against it on such grounds.

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IN WITNESS WHEREOF the Parties have executed this Agreement by their duly authorized signing officers.

City of Hamilton

_____

Per: , Mayor

_____

Per: , City Clerk

I/We have authority to bind the corporation.

McMaster University

_____

Per:

_____

Per:

I/We have authority to bind the corporation.

Schedule "A" – Business Plan

FRAUNHOFER-GESELLSCHAFT

Fraunhofer Project Centre BEAM

Fraunhofer Project Centre for Biomedical Engineering and Advanced Manufacturing at McMaster University

Dr. Dr. Johannes Boltze
Dr. Jonathan Bramson
Christopher Oelkrug M. Sc.
Dr. John Brennan

July 30, 2014

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1 Executive Summary

1.1 Undertaking

McMaster University (McM; Hamilton, Ontario, Canada) and the Fraunhofer-Gesellschaft (FhG) operating through its wholly owned Institute, Fraunhofer-Institute for Cell Therapy and Immunology (Fraunhofer IZI; Leipzig, Germany) are establishing a joint project centre in Hamilton to develop novel technologies and products for cell therapy and point-of-care diagnostics. The new Fraunhofer Project Centre will be named the "Fraunhofer Project Centre for Biomedical Engineering and Advanced Manufacturing at McMaster University" ("FPC") and will be an integral part of the new Institute for Biomedical Engineering and Advanced Manufacturing hub (Institute) at McMaster University. The overall objective of the Institute is to become one of the key drivers in Hamiltons's strategy for its Life Sciences Industry cluster, and will carry out applied R&D in the areas of cell therapies and biomaterials. This business plan focuses on the Fraunhofer Project Centre.

Once operational, FPC will be a centre for applied research and development in life sciences and biotechnology with special emphasis on advanced procedures for manufacturing cells, as well as products comprising patient-specific and functionalized (stem) cell preparations for therapeutic use, biomolecules, devices and support structures for bioanalytics, clinical diagnosis and therapy.

The development of the Fraunhofer Project Centre will capitalize on the strength of each institution in developing innovative technologies for biomedicine. Fraunhofer IZI offers significant experience in cell therapy development and Good Manufacturing Practice (GMP) cell production. In this field, medical and economic demands have started to cause an urgent need to increase output quantity, quality and speed at reduced costs. At the same time, cell therapies are envisioned to move beyond the current state of the art by providing tailored, e.g. patient- and disease-specific (stem) cell preparations and by utilizing of bioengineering techniques to enhance cell treatment safety, tracking, applicability, and efficacy. Fraunhofer IZI conducts research covering these aspects and being foreseen to result in novel biomedical products.

Both partners will bring expertise in medicine and engineering to FPC which will develop a new industry around manufacturing: the instruments, systems management tools and sterile environment enclosures that will be required by companies around the world to take on the challenge of personalized cell therapies at the most advanced stages. Hence, the joint creation of FPC represents the nucleus of that new industry with the potential for development partnerships with industry and the birth of spin-off companies

to commercialize new technologies. Further, the cutting-edge biosensor technologies available at McMaster and Fraunhofer IZI will serve as a keystone of our automation efforts by enabling real-time monitoring of the cell production processes. The establishment of large-scale manufacturing methods for these biosensors in FPC will provide a secondary platform for business development in the area of point-of-care diagnostics, including those that can be used to monitor the cell therapies, ultimately broadening the joint venture's business opportunities.
By attracting visiting scientists and industry researchers from around the world, FPC will increase both institutions' as well as Ontario's reputation for excellence in research and commercialization in the international environment. Moreover, the close collaborative relationship will bring these novel discoveries and business opportunities to the German and EU communities and augment the profile of Germany as a leader in this emerging area of biotechnology. Ontario's goal of creating a business-friendly climate will be furthered by the development of the Centre, which will allow German and Canadian personnel to work in collaboration and with partners from the private sector, while the Fraunhofer-Society will sharpen its internationally recognized profile as a highly competitive institution for applied research.

1.2 Financing

McM will provide resources for the facility and equipment in the initial (transitional) phase which is planned to last from 09/2014 to 12/2015. During this phase, FPC will be backed by investment comprising funds for the office and laboratory building at the McM Innovation Park (to be finished by 2016, for funds see **chapter 10** and **Figure 5**) as well as initial project work. Furthermore, joint research projects initially valued at $4.0 M over 5 years are being applied for through public sources and the acquisition of further industrial contracts will start soon. Once operational, FPC will attract a significant and steadily increasing amount of funds from the private and industrial sectors, particularly in form of contract research activities.

Exchange of research personnel and material in the context of joint projects is explicitly planned. Subcontracts to Fraunhofer IZI within industry-driven projects will be realized as they are offering an additional benefit to FPC and its customers.

1.3 Organization

FPC will be a research institute created within McMaster (i.e. FPC is not a separate legal entity), and will be governed under a frame work agreement between McM and Fraunhofer, in accordance with McMaster's policies. It will be operated by a management team of two scientific directors and two assistant directors, each appointed by either side. They will be supported by

and report to a supervisory board headed by the Vice President, Research (VPR) of McM and the Director of Fraunhofer IZI. The Supervisory Board will further include experts from related research faculties and the central administrations of both McM and FhG with equal numbers from both sides. The VPR of McMaster reports to the Senate and to the board of governors of McM and the Director of IZI reports to the Fraunhofer Board of Directors. Adequate controls also have to permit compliance with both German and Canadian legal and other regulations.

FPC will be counselled by an Advisory Board comprised of experts from industry (6 members) and academia (3 members) to be appointed by the management team on the basis of proposals for candidates from both Fraunhofer and McM.

Fraunhofer IZI will establish a mirror structure to FPC FPC at its Leipzig institute (Fraunhofer IZI mirror group) to support the activities of FPC FPC within the cooperation. The Fraunhofer IZI mirror group shall contribute to the cooperation by preparing experimental settings and incentives for collaboration, by organizing complementary initiatives in particular by sharing specialized animal models, knowledge on GMP manufacturing processes and regulations, induction of pluripotent therapeutic cells and by realizing access to special equipment such as its recently established bio-nanocenter as well as sophisticated imaging facilities.

2 Background and motivation

2.1 Strategic considerations, market review and motivation

Cell technologies and regenerative medicine belong to promising fields of life sciences with a significant scientific, therapeutic and ultimately market potential. Canadian universities have focused interests in these fields. Particularly, McMaster University has developed a strong and sustained life sciences profile with international visibility (Dr. Bramson). Particular activities like the Biointerfaces Institute (Dr. Brennan) comprise not only scientific expertise but, in addition, already good ties with the Canadian biotech industry. However, additional applied research is needed to address the requirements of the North-American biotech industry more directly and increase visibility through a specialized competence centre.

The Fraunhofer IZI is, together with other Fraunhofer Institutes, a member of the Fraunhofer Life Science Group (*Verbund Life Sciences – VLS*) being focused on applied research in the fields of cell technology, cell therapy, immunology, diagnostics and drug development. During the last three years the share of Anglo-American industrial partners within the in-kindthese

collaborations IZI has learned that early financing of innovative concepts and ideas particularly, in life sciences and biotech, is much better organized and driven by a more venturesome spirit as compared to Germany.

Hence, IZI decided to be on qui vive for a renowned North American academic partner institution within a vital and vibrant biotech and life sciences industrial environment. Next to the outstanding public funding environment as well as a research- and investment-affinitive local biotech industry, shorter travel distances, European style cultural affinity and attention with regard to the well-organized biotech sector were arguments to consider a Canadian location, with the Province of Ontario offering an excellent industry-friendly climate. Advice and support by the Canadian Embassy (Trade Commissioner Mr. Schroeter and Counsellor for Science & Technology Dr. Decker, see support letter by the Canadian Embassy Germany) turned out to be very helpful for finding initial contacts in 2012. Representatives of the IZI business development (Dr. Tradler) and the IZI research departments visited several Canadian research centres and finally embarked on McMaster.

Very soon in 2012 not only talks but joint research projects had been initiated which already led to a joint scientific publication[1]. This highly productive atmosphere has initiated sustained considerations at the scientific as well as at the top leadership level to significantly extend the activities, finally resulting in the decision to create FPC with mutual benefit for McMaster and Fraunhofer.

McMaster will contribute expertise in material sciences and surface structuring (Dr. Brennan) and T cell immunology (Dr. Bramson) while Fraunhofer IZI will contribute particular expertise in cell biology and therapy (Dr. Boltze), cancer immunology and biotechnology (Mr. Oelkrug), T cell manipulation for therapeutic purposes (Dr. Emmrich) and process development of cell manufacturing (Dr. Schmiedeknecht). Additional competencies will be integrated from both sides as needed.

The FPC at McMaster and its founding partners bring together a critical mass of expertise, resources and goal-oriented spirit required to bring together the mutual interests to form a FPC Centre with excellent perspectives for successful commercialization of novel procedures and products in the field.

2.2 Scientific focus

With its development programmes and technologies, FPC will combine two general life science/biomedical technology areas of utmost importance for health systems worldwide; Regenerative Medicine and Innovative Diagnostics with Engineering and Automation expertise. This combination, which occurs at the interfaces of technology areas that have until now not

been that closely linked, features, from our point of view, a huge potential for new and innovative products and technologies that can be successfully commercialized.

The FPC will focus with its activities on applied research covering the following areas.

Regenerative medicine and cell therapies:

- development of innovative cell therapy approaches

Automated cell production:

- development and implementation of automation solutions for the manufacturing and quality control of cell based therapies. This also includes the field of specialized diagnostics
- development of diagnostic devices for point-of-care use and novel biosensors for use with such devices as well as quality control purposes for cell-based therapeutics

Various collaborative efforts between McMaster and Fraunhofer IZI groups have been initiated in the last two years. Based on these experiences joint grant applications are in preparation. Their scientific and medical goal is outlined in the following approaches.

2.2.1 Examples for FPC project activities

In this paragraph, a number of innovative research and development projects within FPC are introduced exemplarily, illustrating the scientific focus of the centre. The projects are taken from the areas of biomedical engineering and cell therapy development (**numbers 1 – 4**) as well as advanced manufacturing including biosensor developments (**numbers 5 – 6**).

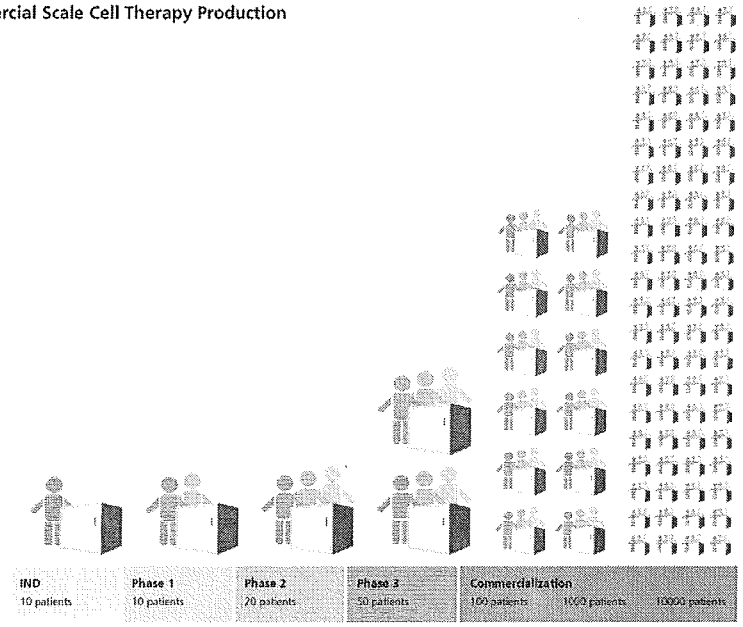
While the advanced manufacturing projects focus on the development of automation and monitoring techniques which can be offered to the industry within a relatively short time frame after FPC startup (1 – 3 years), cell therapy projects deal with the development of novel cell therapy products which are intended to fill the FPC project pipeline in the midterm (2 – 4 years). Also, these cell products can be optimized due to their production using the solutions being developed previously at FPC.

This may finally allow FPC to offer complete biomedical "one-shop" therapy and production solutions to its industrial and academic customers. All shown projects will be conducted in close collaboration between FPC staff at McM and within the Fraunhofer IZI mirror group.

Project 1

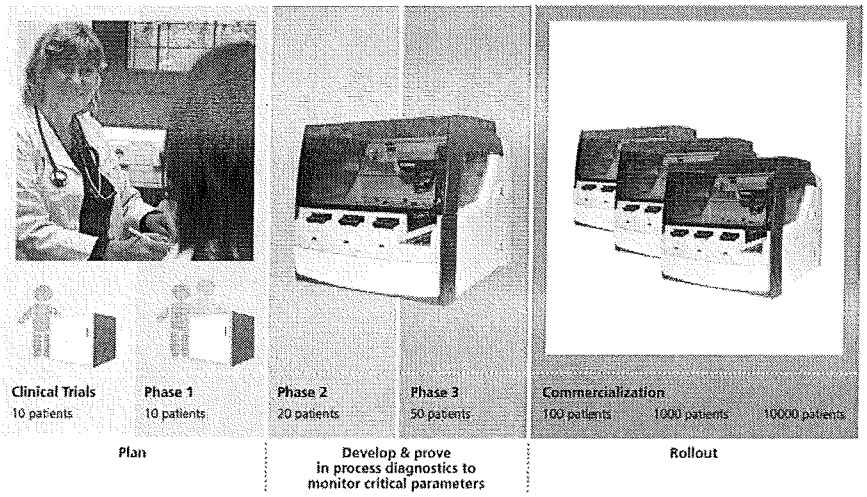
Automation of cell manufacturing

Currently, the manufacture of cell therapies requires a sophisticated GMP infrastructure and highly specialized technicians. While, these boutique operations are critical at the current time to enable clinical evaluation of cell therapies, integration of cell therapies into standard clinical practice will require turnkey instruments that operate without the need for a sophisticated infrastructure or highly trained technicians. GMP scientists from IZI are working with Biomedical Engineers at McM to develop automated, fully closed bio-reactors that will provide a turn-key option for GMP manufacturing with the capacity for simple parallelization of cell manufacturing to enable the simultaneous production of 10s – 100s of cell products. A key aspect of this research project will be the development of in-line diagnostic sensors by IZI and McM scientists that will monitor the cell manufacture and enable real-time adjustments to the culture conditions in a batch-fed mode. We are also exploring the utility of microfluidic concepts and magnetic field technologies for manipulating the cells within the bioreactors to bypass the need for physical manipulation by a lab technician.



Schematic concerning the traditional production of cell based therapies

Our ultimate goal is the development of a modular and scalable platform that can be adapted to the needs for any cell therapy. In our initial project, we will focus on the automation of engineered T cells for cancer therapy. Recent clinical trials have demonstrated the remarkable potency of engineered T cells for treating numerous cancers. As with all cell therapies, current methods for manufacturing engineered T cells rely upon manual laboratory methods that have been adapted to the GMP setting. Current leaders in the field (ex. Novartis) are gearing up large GMP units that will scale the current manual processes; this approach will lead to a high cost of goods, which will ultimately limit the market penetrance of their cell therapies. Through the FPC initiative, we are developing a modular system for the manufacture of engineered T cells that will automate all aspects of the manufacturing process, including separation of the blood products and collection of the end product, which should greatly reduce the cost of goods and make engineered T cells an affordable solution for cancer therapy by a broader range of individuals. By taking a modular approach, we can provide individual modules/diagnostics or the complete system to parties interested in our technologies.



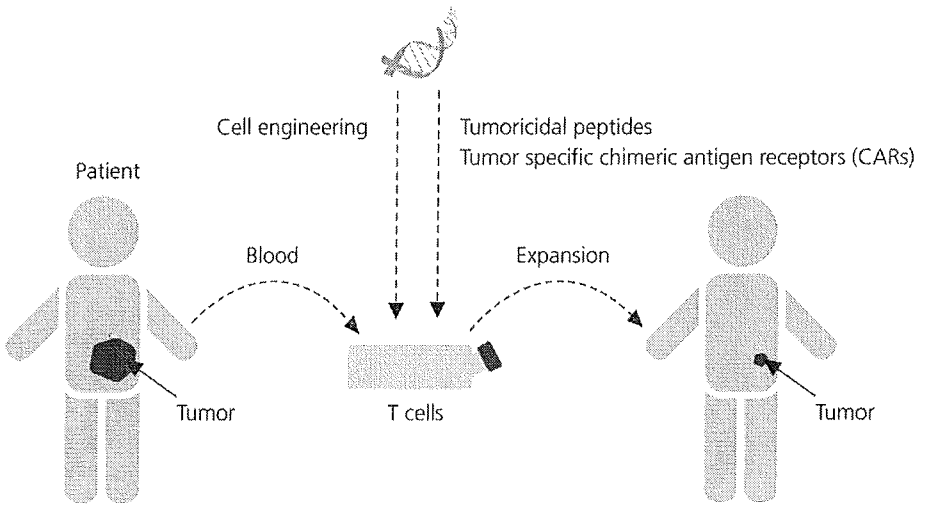
Schematic concerning the automated production of cell based therapies

By developing a scalable manufacturing process alongside clinical evaluation of our novel therapies, we will ensure that a scalable production method is in place at the time our cell therapies are ready for deployment to the marketplace.

Project 2

Development of immunotherapies for oncology

The increasing prevalence of oncological diseases necessitates a breakthrough in the discovery of efficient and affordable therapeutic procedures. The so-called tumor vaccines including cell therapy present an alternative to the treatment strategies used until now, such as chemotherapy and radiation therapy which are associated with significant side effects. Furthermore, chemo-resistance of cancer cells plays a pivotal role in the development of novel secondary treatment concepts for cancer patients. It is becoming clear that cancer cells can differ greatly in their susceptibility to T cell lysis. Thus, even a robust vaccine will fail against a tumor, which can resist T cell attack. The McMaster group has developed a high throughput screening method to identify compounds that sensitize tumors to lysis by T cells.



Schematic concerning the development of immunotherapies for oncology

The Immunotherapy/Oncology Unit at Fraunhofer IZI has developed novel peptide libraries that will be tested for their capability to sensitize tumor cells to T cell lysis. Such peptides may have inherent tumoricidal activity or they may trigger pathways that complement the cytotoxic effects of T cells leading to enhanced tumor killing. Successful hits from this screen will be useful adjuvants for all forms of immunotherapy, including vaccines, adoptive T cell therapy and checkpoint blockade. In a next step, these *immuno-sensitizers* will be used to generate genetically engineered T cells that will secrete these specific peptides at the tumor site. This technology will also be coupled with engineered naïve T cells to express tumor-specific chimeric antigen receptors (CARs), bypassing the need to select rare tumor-specific T cells.

Moreover, Fraunhofer IZI has experience in preparing dendritic cell vaccines for cancer treatment in various indications according to GMP guidelines. Valuable information has been provided to the management team on engineering demands regarding improved protocols and supportive devices for automation.

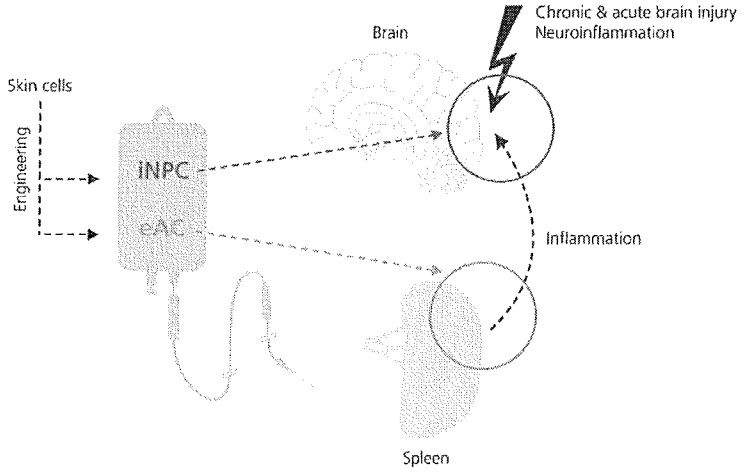
Project 3

Cell therapy for Neuroinflammation

A substantial body of evidence suggests that intravenously transplanted cells could ameliorate severe organ injury such as cerebral stroke, myocardial infarction and spinal cord injury. Interestingly, it was shown that therapeutic efficacy was abolished in animals that were splenectomized prior to cell therapy. We hypothesize that intravenously transplanted cells interact with the host scavenging system, localized within the marginal zone of the spleen. In fact, it was shown in the steady state that apoptotic cells are phagocytosed in this area, and that this process is important for the preservation of central tolerance. Ablation of this scavenging system resulted in lupus-like autoimmune disorders and loading of apoptotic cells with brain antigens was successful to remedy experimental autoimmune encephalomyelitis, the animal model of multiple sclerosis. The aforementioned scavenging system consists of specialized splenic macrophage populations that secrete large amounts of IL-10 and TGFβ that for their part induce regulatory T cell and Th2 polarization. Protective immune tolerance is moreover mediated by expression of the death ligands TRAIL and PD ligand-1 signalling. In this project, we aim to deepen our understanding of tolerance induction by activation of the splenic scavenging system by transplanted cells. Appropriate selection and subtle pretreatment of cell grafts could potentially enhance this therapeutically important endogenous mechanism.

Targeting the perivascular compartment with neural progenitor cells to treat brain inflammation

The neurovascular niche in the CNS consists primarily of the vessel, a dense glial sheet and an immunologically important compartment between, the Virchow-Robin Space (VRS). This space is the immunological interface between the circulating effector cells and proteins of the immune system and the immune privileged brain on the other hand. Interestingly, the VRS secretes chemokines that are typical for lymphatic tissue such as the CC chemokine ligands (CCL) 19 and 21, and contain predominantly activated central memory T cells expressing the chemokine receptor CCR7 (that is activated by CCL19 and 21). During inflammatory CNS disorders such as multiple sclerosis, hypertension-related vascular dementia, cerebral stroke and traumatic CNS injury, the VRS becomes an important meeting room for CNS-resident immune cells and peripheral effector cells.



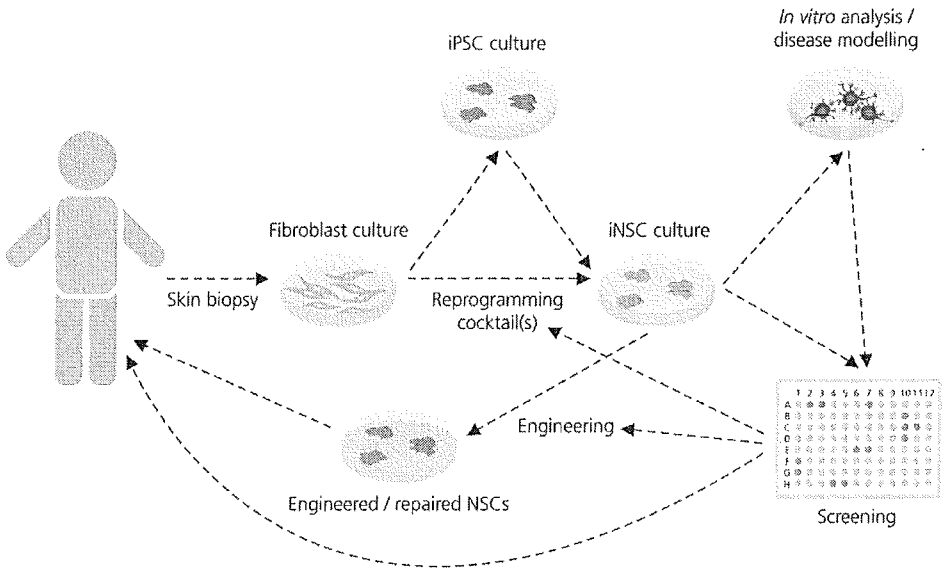
Schematic concerning the development of cell engineering and cell therapy for neuroinflammation

Here, T cells recognize their cognate antigen, become activated and finally cause brain tissue damage. Intriguingly, it was shown that intravascularly transplanted neural progenitor cells were strongly attracted by inflamed CNS vessels and accumulated in the VRS where they persist and suppress T cell activation and induce their apoptosis. This paradigm was proven in experimental autoimmune encephalomyelitis, the animal model of multiple sclerosis, but not yet translated to other types of inflammatory brain damage. In this project, we aim to use tailored autologous neural progenitor cells (refer to the proposal *Cell Engineering*) to treat hypertension-related vascular inflammation (small vessel disease), a disorder that is responsible for every 5th cerebral stroke and almost the half of all dementias.

Project 4

Cell engineering

The discovery of ways to change the fate even of adult cells via reprogramming approaches has opened new avenues for cell therapies and biomedical research. It is now possible to obtain relevant human cells in order to develop innovative cell based therapeutic strategies without major ethical concerns, but also to model and study pathophysiological mechanisms of a wide variety of diseases even in a patient specific manner as well as to identify new therapeutic targets and to analyse effects and side effects of such drugs. We have developed and established strategies to generate neural stem cells (NSCs) from fibroblasts either via an induced pluripotency stem cell (iPSC) intermediate or via direct conversion. These methods are currently being optimized to increase efficiency, quality and viability. To this end, we focus on identifying new programming factors and their combinations as well as culture and differentiation conditions to improve cell programmability (medium, growth factors, and small molecules).



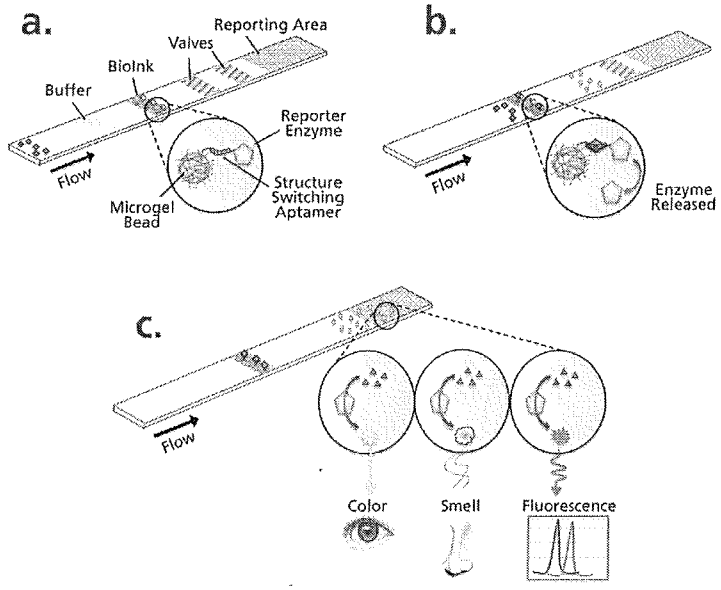
Schematic concerning the development of NSC based therapies

In order to successfully establish NSC based therapies it will also be necessary to improve functionality of these cells. Therefore, clinically applicable methods are being developed to increase migratory capabilities and responsiveness to disease specific signals as well as to secrete additional factors. To engineer such bespoke cells, i(PSC)NSCs and their derivative cells (neurons as well as astrocytes and oligodendrocytes) will be used to study and model the disease process. This in turn may also allow identifying new targets and screening compounds for beneficial purposes.

Project 5

Biosensors for in-process monitoring

Problem Statement: In spite of tremendous research progress in the last several decades in the area of biosensors3-5, there are currently no commercially-available biosensing systems that can be used at the point-of-care (POC) to rapidly monitor bioprocesses or detect key markers associated with infectious disease, heart disease, cancers, and so on. The major hurdles in moving these systems from the research laboratory to the market are two-fold: 1) the lack of a method to rapidly develop and optimize biosensing systems in a manner that is amenable to scale-up (i.e., though printing of sensing components and biological elements onto suitable surfaces) and; 2) the lack of inexpensive, rapid and scalable manufacturing processes for producing and integrating essential components of a miniaturized biosensing system. Such components include: (1) printable solid-phase electronics, (2) printable biorecognition layers that can be placed at the solid-liquid interface and (3) printable ancillary components to produce complete sensing systems in a scalable and easily manufacturable process. Producing a pipeline that addresses the production, scale-up and manufacturing of diagnostic systems is the key goal of the FPC initiative.



Target-Dependent Release of Reporting Enzymes from Bioinks (DERBI): (a) The liquid containing the target moves towards the bioink area, passing through to a pullulan-based printed buffer-film ; (b) the target displaces the reporting enzyme and if needed, pullulan barriers will be printed to delay the flow in the strip to allow extensive interaction between the target and the bioink; (c) the reporting enzyme moves to an area where the substrate is present, developing a signal (colour, smell and/or fluorescence).

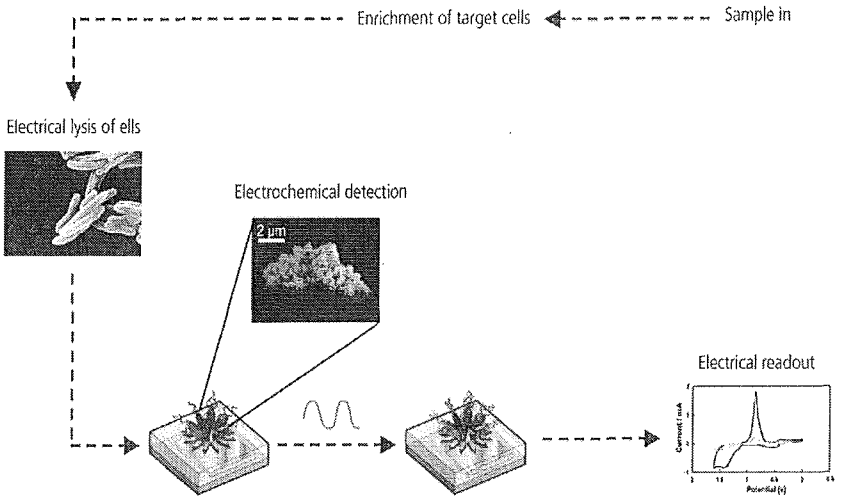
The Solution: Our vision is to create a platform that will utilize printing technologies from the beginning to the end of the sensor development process to produce a scalable, manufacturing-ready POC diagnostic production system that will accelerate the translation of POC tests to the market. The key aspect is to develop a highly controlled printing-based, advanced manufacturing platform that can allow us to create, on an on-demand basis, several key POC components including those for: 1) sample preparation and manipulation (including a novel microfliuidic system with selective surfaces to allow sample clean-up, printable reagents for manipulation of cells (lysis, selective extraction) or other analytes, mixing systems, etc; 2) Selective capture (or turnover, as needed) of the analyte of interest, typically though printing of biological recognition elements or MIPs, with surfaces engineered to eliminate interferences from non-specifically bound compounds; 3) Signal generation, though integration of printed reagents that produce colour, emission or electrochemical signals, or by integrating signaling elements into the initial biorecognition elements (e.g. signalling aptamers); 4) Amplification of the initial signal by incorporation of either passive or active signal enhancement technologies (see below) and 5) easily interpreted outputs (bar codes, patterns, numerical outputs) that can be read by eye or using a smartphone app. Integrated into this platform will be ancillary activities related to generation of reagents at a scale suitable for production of prototypes, and

preliminary validation studies for regulatory purposes and to provide feedback for improvement of diagnostics.

Project 6

Application of novel sensor techniques for low cost diagnostics

The development of molecular diagnostic test systems for the sectors food and medicine / clinical practice plays a pivotal role in point of care diagnostics. A major target of this unit is the implementation of sample preparation steps (e.g. pathogens from blood, urine, sputum or saliva) onto diagnostic devices. In the first place, a novel lab-on-a-chip diagnostic platform (see graphic below) will be implemented on the basis of functionalized magnetic particles. After an optional amplification, the target sequences will be detected via hybridization to specifically coated, nanostructured electrodes. The technology developed – next to optical strategies - will be adapted to enable the process monitoring of bioreactors and cell culture automation. Latter will be beneficial to the cell manufacturing market.



Schematic concerning the development for low cost diagnostics

An additional focus is the development of low cost test strip-based tools for the detection of neglected diseases. The aim of the project is the integration of DNA amplification and detection on a single, simple strip. Here, relevant samples can be saliva- or urine borne pathogens, which will be isolated and lysed on-strip.

It is important to mention, that development programmes in regenerative medicine and diagnostics are not representing separate development lines but are closely interconnected. Thus, the development of innovative biosensors in the diagnostics programme line will for example allow not only the development of innovative point of care (POC) diagnostic devices as companion diagnostics to monitor cell therapies, but also represents an important aspect within the development of automation solutions for manufacturing of cell based therapies as it is of utmost importance to integrate quality assurance systems, considering for instance the importance of vitality and differentiation status of the cultivated cells during an automated manufacturing process.

3 Goals and strategic value for Fraunhofer and McMaster

Strategic value for McM is ensured by channelling academic concepts and achievements towards economically attractive applications. An internationally renowned branding and the experience in applied research and development (R&D) of Fraunhofer would be of strategic value not only for FPC but also for the entire McMaster University by enhancing attractiveness for students and highly qualified academic staff as well as in form of additional contributions to education by scientific FPC personnel.

Fraunhofer benefits from an intensified access to the North American biotech and life sciences R&D market, providing outstanding strategic value and perspectives. Attractive funding options and highly motivated entrepreneurs together with a considerable market volume are excellent prerequisites for successful developments and commercialization projects that will be adapted, finalized and offered via FPC. According to resources, knowledge and know-how contributed to the joint initiative, there will be a return to initiators by FPC not only in form of scientific discovery and translation, fund raising opportunities and industrial support ("soft" return on investment, ROI), but also in form of intellectual property (IP) rights including licences fees as well as marketable products providing "hard" ROI for McM and Fraunhofer.

3.1 Goals for the transitional phase (09/2014 – 12/2015)

Initial FPC office and lab space will be provided by McM at Dr. Bramson's institute. First applications for public funding (e.g. with the Ontario Research Fund, ORF) are being prepared and funding decisions are expected for early 2015. After a positive decision by the Fraunhofer Board of Directors, being expected by August 18th 2014, work in joint projects will start in late summer 2014 being governed by specific contracts when required and conducted by personnel contributed by either side. All contract documents are targeted to be finalized and signed shortly after a positive decision by the Fraunhofer Board of Directors. Particular goals for the transitional phase comprise:

- implementing the FPC leadership and supervisory structure, sustaining the close collaboration between both institutions, implementation of the FPC advisory board
- launching publically funded, joint research activities to create first IP products

- creating strong awareness among the North American biotech industry and academic partners (scientific publications, workshops, exhibition, business forums)

- establishing and extending a customer's network and initiation of first industry-funded contract research activities

- increasing project acquisition and output to meet the mid-term evaluation criteria

- finalizing completion of permanent facilities for the stationary phase as well as securing public and industry funding to fully utilize its capacities

Goals will be translated into success criteria as outlined in **chapter 9**.

3.2 Goals for the stationary phase (01/2016 – 04/2019)

Stationary phase will see a continuous growth of projects and personnel in the FPC laboratories at the McMaster Innovation Park (MIP). Extraordinary success in acquisition of contracts permitting, there will be a stepwise increase in activities and, potentially, also space. FPC is expected to grow significantly until 2019. Particular goals for the stationary phase comprise:

- substantial growth based on excellent reputation and success, further increasing of awareness among the industry and academic institutions

- further sustaining interconnection between FPC and Fraunhofer IZI in the form of joint projects

- close collaboration with industry including support of smaller companies which may be present on site

- securing increasing amounts of contract research with the industry

- generating revenues by licensing IP and commercializing products

- conducting well-selected, strategically important, publically funded projects to develop additional products to fill the FPC pipeline

- spin-off companies will sustain FPC's commercial success

- meeting long-term evaluation goals and preparing for permanent activity or even, success criteria permitting, upgrade to a Fraunhofer Centre

Goals will be translated into success criteria as outlined in **chapter 9**, which also comprises numerical details for the expected growth.

4 Partners, competencies and collaboration concept

4.1 The Fraunhofer-Gesellschaftand Fraunhofer IZI competencies

The Fraunhofer-Gesellschaft ("Fraunhofer" or "FhG") focuses on people's needs in all aspects. Research and its application to benefit society is their major goal. With a workforce of over 23,000, the Fraunhofer Society is Europe's biggest organization for applied research, and currently operates a total of 67 institutes and research units. The organization's core task is to carry out research of practical utility in close cooperation with its customers from industry and the public sector. In this way the Fraunhofer Society shapes the innovation process in Germany and drives forward the development of key technologies. The organization's research focuses on the needs of people in the areas of healthcare, security, communication, mobility, energy and the environment. Fraunhofer's international sites and its representative offices act as a bridge to the regions of greatest importance to scientific progress and economic development.

The **Fraunhofer Institute for Cell Therapy and Immunology IZI** is one of the youngest, but largest and most vibrant members of the Fraunhofer Life Science Branch. Currently employing almost 400 scientists, technicians and post-graduate students at 4 different locations throughout Germany, the Fraunhofer IZI is particularly dedicated to transferring biomedical technologies from the bench to clinical application. Its expertise spans a wide range of fields being highly relevant for technology transfer. Of particular importance for FPC are the areas of cell therapy, GMP production and diagnostics, as represented by the particular departments. In all of those, IZI is working at the forefront of applied research and is highly renowned both in the European Union and overseas. The scientific expertise at IZI has not only attracted some of the internationally most renowned companies as customers and partners to the institute, it has also consolidated close collaborations to leading academic medical institutions including the Charité and groups/departments at Stanford, Harvard as well as the Chonnam National University in South Korea next to McMaster University. A detailed list of the IZI's core competencies with particular relevance to FPC is given in **Appendix A**.

4.2 Competencies of McMaster University

McMaster University is home to some of the country's and even indeed the world's most advanced research institutes, centres and facilities. Spread across the disciplines are more than 100 research units pursuing new opportunities in strategic areas, engaging with industry to move research out of the lab and into communities where it can change lives for the better.

In its initial stage, FPC will be directly tied into 2 of the university's strongest research groupings: the McMaster Immunology Research Centre and the Biointerfaces Institute:

The **McMaster Immunology Research Centre (MIRC)** occupies 36,000 sq ft of space on the 4th and 5th floors of the Michael DeGroote Centre for Learning and Discovery and is home to 12 principal investigators, 5 research associates, 108 research trainees, 33 research technicians and 3 administrative assistants. MIRC scientists study immune regulation at the mucosal tissues which stand between internal organs and the environment. Research from the centre has spawned a novel vaccine for tuberculosis, innovative methods for cancer treatment, new perspectives on the mechanisms and treatment of food allergy, and creative strategies to prevent and manage lung disease. With regard to FPC, MIRC scientists are developing novel cell therapies for cancer that provide a feeder stream for technologies that can be commercialized by FPC. Further, the infrastructure that has been developed within MIRC for clinical trials of cancer cell therapies is unparalleled in Canada and provides an ideal conduit for evaluation of FPC's novel manufacturing technologies.

The **Biointerfaces Institute (BI)** occupies 10,000 sq ft on the 4th floor of the Engineering Technology Building and consists of 10 core principal investigators, 15 associate members, 7 technical staff and 2 administrative staff. The BI supports the research of >150 postdoctoral fellows, graduate students and undergraduates. The Institute has the ability to rationally and rapidly develop new biomaterials with surfaces engineered to have the appropriate interactions with the intended biological environment. Using the latest technologies in high-throughput synthesis and screening to prepare and screen biointerfaces and biomaterials, the facility utilizes state-of-the-art equipment with dedicated, professional research scientists. The ability to prepare and characterize thousands of different materials on a surface the size of a microscope slide combined with the potential to know almost immediately how an artificial material might react with biological entities, will lead to the accelerated development of better biosensors and better medical implants. The institute is available as a testing lab for industrial partners and as a centerpiece for the development of biosensors and diagnostics to aid in commercialization of sensor technologies. The Biointerfaces Institute is a world leader in the development of advanced sol-gel based biomaterials, biosensor technologies and high-throughput drug screening platforms and has ten additional core faculty members with expertise in high-throughput synthesis, surface characterization, polymer chemistry, bioassay development and ophthalmic biomaterials, with backgrounds in Chemistry, Chemical Biology, Biochemistry, Chemical Engineering and Biomedical Engineering. The technologies and scientific expertise within the BI will prove to be central to the success of FPC as sophisticated sensor technology will be required for optimizing automated cell production and the low-cost disposable biosensors produced at the BI provide a platform for innovation in the manufacturing of point-of-care diagnostic devices.

Further information on McM centres with relevance to FPC is provided in **Appendix B**. The IZI and McM core expertise will merge into FPC, thereby creating a unique professional centre for applied research, being ideally suited to partner with the biotech industry (see **Figure 1**).

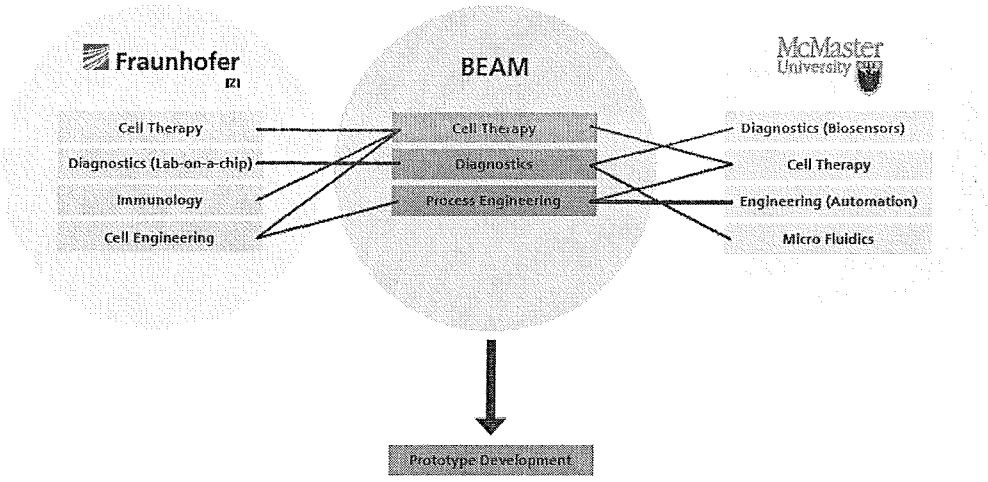


Figure 1: Core competencies of Fraunhofer IZI and McMaster

4.3 Concept for Collaboration

McMaster University and Fraunhofer IZI intend to unify their unique expertise in two distinct business areas which both partners foresee to be relevant for the upcoming commercialization of innovative regenerative therapies currently being investigated. The bottleneck of late scale clinical testing and full scale market commercialization of cell therapies will be the availability of GMP cell production technologies enabling production of 100s to 1,000s of cell batches. Current manufacturing in clean room cell culture laboratories is too labor-intensive and does not allow required output quantities. FPC will develop new tools to enable such techniques to be implemented in the GMP cell manufacturing industry. Next to this, FPC will develop advanced cell therapies and generate related intellectual property (IP) by combining research excellence in such therapies and applied systemic immunology for second generation cell therapies to be commercialized in parallel. Details regarding the research and business strategies are provided in **chapters 6 and 7**.

To take advantage of the more venturesome North American market with higher average financial resources being available with the biotech industry to be invested in such late stage applied research, FPC will be established at McMaster University in Hamilton, Ontario. There will be a double

leadership structure, implementing the core capabilities from both institutions into the centre through the cooperation.

During the initial (transitional) phase, a significant amount of public and institutional funding offers the opportunity to generate core IP. The close interaction between both partners from the beginning is foreseen to swiftly lead to such joint developments which the partners will commercialize via FPC to both the European and North American markets at later stages. Hence, the research activities will switch to be mainly driven by industry within 3 to 4 years.

However, due to the high level of specialization in the addressed business areas, not all projects can be conducted solely in Canada, nor can all enrolled IZI scientists be present continuously in Hamilton. Hence, FPC and/or customers will contract Fraunhofer IZI for subproject parts to be optimally conducted in Germany, tax regulations permitting as relevant.

Both partners will also motivate European (e.g. German) small and medium-sized industrial partners to establish subsidiaries in North America. FPC will support this by specialized service offers to such companies, facilitating the start of their business activities in North America and penetrating the local markets. Activities will be performed by FPC personnel (affiliated to McM) and will comprise support in form of consultancy regarding the local market, joint exploration of potential business opportunities or establishing first contacts to Canadian academic and industry leaders. FPC may also exhibit prototype or technologies developed by those partners, but FPC will clearly not act *per procura* or even as a legal representation for such companies.

This service and support is foreseen to further propel FPC activities, as it will result in additional contract research activities and collaboration being requested by these companies once being present in Canada. Moreover, spin-offs are envisioned to emerge from FPC as product and process development as the centre proceeds.

A number of personnel exchange and incentive (initial project support) measures will foster collaborative research right from the beginning. Those are expected to substantiate the cooperation between McMaster University and Fraunhofer IZI. FPC will have its own research facilities in Hamilton from the beginning of 2016. At this time, the project throughput can be increased significantly.

5 Market and opportunities

5.1 Market overview

The Canadian life sciences sector is an important contributor to Canada's innovation economy, engaging in creating the medical innovations that will improve health-care delivery and patient care in Canada and abroad.

5.2 The Canadian life science market in general

The Canadian industry spans the research, development and manufacturing continuum. Industry players include small and medium-sized companies developing diagnostics, biopharmaceuticals, pharmaceuticals and medical devices, as well as global companies with research, development and manufacturing operations in Canada, serving both domestic and international markets. Canada's world-class health research institutions and research networks are integral partners in research and knowledge translation. The Canadian pharmaceutical sector has one of the most lucrative markets. It's the 8th largest market in the world with continued growth. Canada uses effective innovative products to significantly benefit the health of Canadians. Of particular importance are investments in the field of regenerative medicine (see **Figure 2**).

PROVINCE	UNIVERSITY
BRITISH COLUMBIA (BC)	
	Simon Fraser U.
	U. British Columbia
	U. Victoria
ALBERTA (AB)	
	U. Alberta
	U. Calgary
SASKATCHEWAN (SK)	
	U. Saskatchewan
MANITOBA (MB)	
	U. Manitoba
ONTARIO (ON)	
	Carleton U.
	McMaster U.
	Queen's U.
	U. Guelph
	U. Ottawa
	U. Toronto
	U. Waterloo
	U. Western Ontario
	York U.
QUÉBEC (QC)	
	École polytechnique de Montréal
	McGill U.
	U. Laval
	U. Montréal
	U. Québec à Montréal
	U. Sherbrooke
NOVA SCOTIA (NS)	
	Dalhousie U.
NEW BRUNSWICK (NB)	
	New Brunswick Heart Centre
NEWFOUNDLAND & LABRADOR (NL)	
	Memorial U.

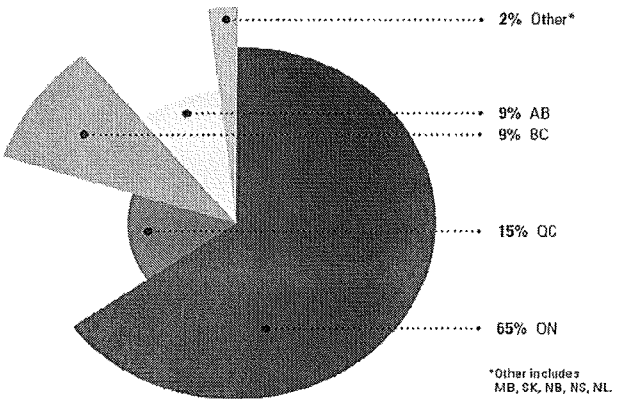


Figure 2: Canadian asset map for regenerative medicine (total funding from 2005 to 2011: US$277.5M). Please note the outstanding participation of the Province of Ontario, contributing two thirds of shares in the field.

The pharmaceutical sector makes a significant contribution to the Canadian economy. According to Statistics Canada, drug manufacturers employed 27,000 Canadians, shipped $10.5 billion worth of goods manufactured in Canada, and contributed almost $4.6 billion to Canada's Gross Domestic Product in 2012. The pharmaceutical industry in Canada has close access to the U.S. market, which received 74 percent of Canadian pharmaceutical

exports in 2012. There is also considerable activity performed by the pharmaceutical sector in other value-added areas including wholesale, distribution, research and development and regulatory compliance. Taking into account all these activities, the Canadian pharmaceutical sector employed close to 70,000 people, many of whom are highly skilled and requiring a post-secondary degree. The industry is also a significant R&D performer, conducting around 10 percent of all Canadian business research and development.

The Canadian biopharmaceutical pipeline includes highly innovative and promising product candidates in various therapeutic fields. There are about 110 Canadian biopharmaceutical small and medium enterprises (SMEs) with over 325 promising biopharmaceutical products in human health under development. About 75% of Canada's biopharmaceutical products are in the early stages of R&D, (i.e., research to phase I/II), while another 25% are in mid- to late- stages of development (i.e., late-stage clinical trials). Canadian companies, over time, have advanced over 65 products into phase II development and another 15 are in phase III clinical trials as of March 2014. A small number (8) of Canadian products are on the global marketplace. Promising future fields are summarized in **Figure 3**.

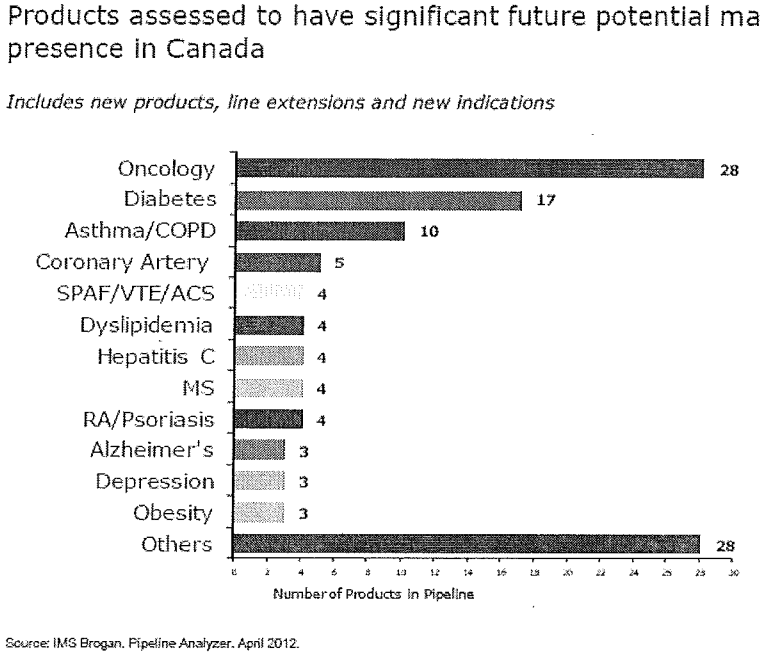


Figure 3: Potential markets for new developed products in Canada. FPC will particularly focus on oncological and neurological applications.

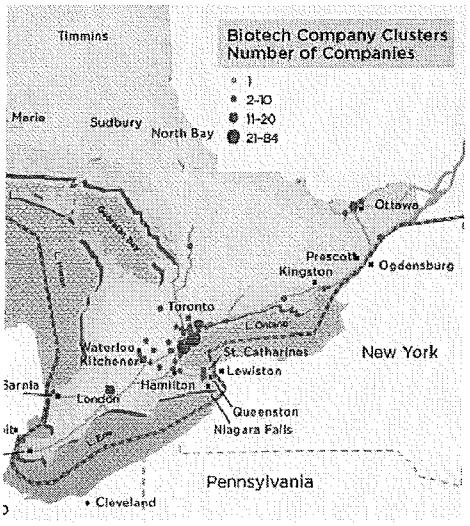
Canadian biopharmaceutical SMEs have strengths in oncology, with 40% of the industry's products in development in this category. The second most intensive field of investigation by Canadian companies is in the area of central nervous systems (CNS) disorders, which claims almost 20% of

products in the pipeline. FPC will particularly focus on these activities, as the scientific excellence among McM and Fraunhofer IZI is most pronounced in these fields.

5.3 The Ontario life science market

As Canada's economically most vibrant province, Ontario enjoys attention among the biotech industry, resulting in one of the world's largest densities of biopharmaceutical companies in Southern Ontario (see Figure 3).

Biotech companies



Medical devices companies

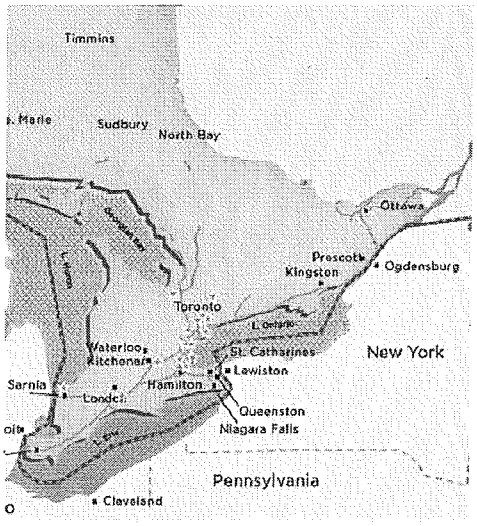


Figure 3: Maps displaying biotech and medical devices companies in Ontario. Please note the strong presence of companies in the Hamilton/Toronto area

This has led to significant investments by both large pharmaceutical players as well as small- and medium-sized companies. Some of the most prominent examples are given below.

GE Healthcare is establishing its Global Pathology Imaging Centre of Excellence at the MaRS centre in downtown Toronto (69km, 50 min from FPC). The $10 million centre will focus on developing innovations in digital imaging, workflow and computer-aided diagnostics that will improve patient care and reduce health care costs.

GlaxoSmithKline has begun a $33.6 million expansion of its state-of-the-art manufacturing facility in Mississauga (49km, 35 min from FPC) and launched the $50 million GSK Canada Life Sciences Innovation Fund to invest in early stage Canadian research.

Novartis Pharmaceuticals is partnering with the Population Health Research Institute, Hamilton, for a $100 million global clinical study of a new high blood pressure drug that will involve more than 11,000 seniors in 20 countries.

Novocol Pharmaceuticals is investing $54 million to expand production and R&D capacity at its Cambridge (45km, 41 min from FPC) facility.
Roche Canada is investing $190 million to establish a new global pharmaceutical development site in Mississauga (49km, 35 min from FPC) to manage all stages of global clinical trials research.

Teva Canada Limited has launched a $56 million expansion of its High Potency Manufacturing Centre of Excellence in Stouffville (120km, 78 min from FPC). Once completed, the facility will be one of the most advanced pharmaceutical plants in North America.

5.4 Personalized medicine

Personalized medicine or treatments that are tailored to the individual represent the future of health care. At the forefront of these personalized treatments are cell therapies, where cells from individual patients are removed, optimized in the laboratory for specific applications and returned to the patient. New cell therapies are being developed for a range of chronic diseases, for example, cell therapies have already been proven effective in clinical trials where cures have been obtained in melanoma and leukemia. These therapies rely upon advanced manufacturing methods to manipulate the cells and transform them into a medical product under stringently controlled conditions. Currently, the manufacturing process relies upon manual techniques, which greatly limits the throughput and significantly inflates the cost to the end user. As such, there is a need to optimize equipment and processes to improve efficiencies in cell therapy manufacturing. The McMaster Immunology Research Centre has significant experience in the area of cell therapies for cancer, having completed 5 clinical trials with autologous dendritic cells. Within their pre-clinical group, MIRC is also developing novel strategies to engineer T cells with the ability to kill tumors and is ready to translate those discoveries into clinical trials. These novel cell therapies will serve as an excellent candidate for the development of automated instrumentation for manufacturing. The Stem Cell and Cancer Research Institute is also developing novel cell therapies for degenerative diseases, which will provide a pipeline of therapeutics for FPC and suitable test cases for continued refinement of FPC's automated manufacturing processes. Further, there has been significant investment in the area of cell therapies but most of the investment is centred on clinical development. FPC will engage corporate partners to develop automated manufacturing solutions for their lead products.

In the area of Point of Care (POC) diagnostics, there is a significant amount of research activity at McMaster University and other Canadian universities, as well as in a number of small and medium sized companies in Canada. However, while biosensors and other point-of-care diagnostics have been studied for over 50 years, only glucose and pregnancy tests are widely available as products. In part this is due to difficulties in optimizing sensors for stability and performance, and in part due to a lack of scalable manufacturing capability. Indeed, several smaller diagnostic companies utilize a manual production method or are forced to adopt simple lateral flow formats that allow semi-automated manufacturing. Within FPC, we will address both of these issues. Firstly, in collaboration with the Biointerfaces Institute, we will provide a service for development and optimization of sensor surfaces that will lead to more rapid prototype development. Secondly, FPC will work with several private sector partners to develop highly automated printing-based manufacturing solutions for full automation of sensor production.

5.5 Cell Therapeutics: a market characterization

The global market for cell therapy was valued at USD 2.5 Billion in 2012 and is expected to reach USD 8 Billion by 2018. The revenue and growth expectations of this industry is driven by several factors, including: recent market introductions of cell therapy related products, increasing patient incidence of diseases and related lack of effective treatments, as well as continuous advances and developments in this field.

However, industry experts also acknowledge that in order for the potential of cell therapies to be realized, it will require significant advancements in technology in the cell therapy market. It is noted that "among the emerging trends of the global market, the most prominent one is the development of sophisticated automation devices for cell expansion and culture processes which could be used in the treatment of life threatening diseases"[2].

5.6 North American cell therapy market

North America is one of the leading regions for cell therapy companies. Estimates indicate that in the five year period from 2013 to 2018, industry revenue will increase at an average rate of 18.1% per year to $2.4 billion[3]. It is expected that during this period, the industry will benefit from lessons learned from preceding clinical trials and the research and development that has taken place over the past five years. A further driver for the growth of cell based therapies is the FDA's Safety and Innovation Act[4] (effective July 2012), which accelerates the approval process for drug manufacturers, including regenerative medicine products.

The number of companies involved in cell therapeutics, and drugs entering approval phases continues to grow. In the five years leading up to 2013, IBIS World estimates that the number of cell therapeutic firms has increased at an average annual rate of 4.4% to 146%. This has ultimately led to an increase in the number of drugs approved over the past five years, with six cell therapy products achieving regulatory approval in the United States[5].

It should be noted that although an increase in the number of products available to patients has caused significant revenue growth over the past five years, growth has not been as expected for some products. A case in point is Dendreon's Provenge. Provenge was approved in 2010 to treat late-stage prostate cancer and was later approved for coverage by Medicare in 2011. This announcement led to speculation that Provenge would be the industry's first blockbuster product. However, the pricing (US$ 93,000 per treatment) has deterred many doctors from recommending the therapy. The Provenge situation is a demonstration of a scenario where streamlined manufacturing processes, enabling cost efficiencies leading to reduced cost to the patient could drive wider market adoption of cell therapeutics.

Cell therapies for cancer are perhaps the most advanced products in the clinic. In addition to Provenge, which is already on the market, there are multiple cell therapies reaching late-phase clinical trials (ex. Argos' Arcelis immunotherapy for renal cell carcinoma, Northwest Biotherapeutics DCVax-L for glioma). The more advanced cell therapies employ a specialized class of immune cell, known as a dendritic cell, to stimulate white blood cells, known as T cells, to fight the tumor. More recently, significant progress has been made in the engineering of T cells for direct application in cancer patients, which bypasses the need for dendritic cells. The most promising area of T cell therapy is the treatment of leukemias using T cells engineered to express chimeric antigen receptors (CAR). It is expected that treatments utilizing CAR technology will enter the market within the next 2 – 3 years. The promise of this approach is evidenced by the significant investments in the last year. For example, Juno Therapeutics and Cellectis, who are both focused on developing CAR-engineered T cells, recently secured US$176 M and US$28 M, respectively from private investors. Additionally, Novartis, who in-licensed CAR-T cell based technology from University of Pennsylvania for US$20 M, has invested an additional US$43 M to purchase manufacturing capacity for their cell therapy directed at treatment of leukemia. Analysts predict that if a method can be developed to efficiently deliver CAR-T cell therapy to the broader patient base, there is the potential for this product "to generate revenues of US$10 billion/year, if approved to treat multiple forms of cancer [6]." With approximately 75 registered clinical trials with cell-based immunotherapies to treat cancer, the potential for these types of therapeutics to capture a significant share of the global market for cancer drugs, which is currently at US$77 Billion but estimated to grow to US$143 Billion by 2023 [7].

Another category of the Cell Therapy Industry which has a strong presence in North America is Stem Cell Therapeutics. A recent report indicates that the Stem Cell Therapy Market is poised to grow at a CAGR of 39.5% from 2015 to 2020, to reach $330 Million by 2020 [8].

Several factors are cited as driving this growth, such as extensive government funding and increasing fast-track approval for stem cell therapeutics by the FDA, growing industry focus and increasing private investments into stem cell research, and increasing global awareness about stem cell therapies through various organizations. Further growth opportunities mentioned include emerging markets, emergence of induced pluripotent stem (iPS) cells as an alternative to embryonic stem cells (ESCs), and evolution of new stem cell therapies. It is expected that in 2015, North America will hold the largest share of the global stem cell therapy market. Several key players involved in the development of stem cell therapies worldwide are based in North America such as Aastrom Biosciences, Inc., Celgene Corporation, and StemCells, Inc.

Canadian cell therapy companies are in early stages of drug development; this situation is of particular interest for FPC. Research activities in this area are plentiful and have led to multiple breakthroughs in stem cell science. According to the Canadian Stem Cell Network, 15 of 32 of the most important scientific papers in stem cell research were authored by Canadians[9]. The government and regulatory climate in Canada is very accepting of cell therapeutics, especially stem cell related products. This research, and the ultimate commercialization of research findings, is championed by Canada's Stem Cell Network and the Centre for Commercialization of Regenerative Medicine. Both of these centres are working to increase awareness and funding for stem cell based therapies in Canada. Canada has taken a leadership role in advancing cell therapies through regulatory approval, as Health Canada was the first to approve a stem cell product (Osiris Therapeutics adult stem cell therapy "Prochymal" in 2012). It is anticipated that similar therapies will have a strong likelihood to be approved in Canada, making Canada a top choice for stem cell therapy research and development.

Next to the stem cell market, North America is also a premium location for point-of-care (POC) diagnostics, which may emerge from FPC. Details of the POC market are summarized in **Appendix C**.

6 Business opportunities and model

6.1 Business model in general

The intention of the FPC is to combine core expertise areas from McM and Fraunhofer IZI, thus being able to jointly develop innovative and commercially successful products together with industry partners (**joint development projects with industry partners**).

Next (and besides joint development projects with industry partners), FPC will offer **contract research** opportunities to regional, national and international industry partners.

Moreover, FPC will seek and make use of local, regional and national as well as European funding opportunities in order to develop (in the course of **publicly funded R&D projects** with or without involvement of industry partners) new technologies and product candidates, thus generating IPR and product candidates allowing successful later commercialization with industry partners.

Last but not least, FPC also intends to establish itself as a kind of a **transatlantic business bridge**, thereby supporting the efforts of German small and mid-sized companies to join the Canadian and North American market. The FPC will provide German companies specific offers, on a lease model, with laboratory and office space within FPC, allowing them to establish a first presence and representatives in Canada, and to conduct applied research with FPC scientists on site. This is part of the service offer as mentioned in **chapter 4.3**.

6.2 Business opportunities in regenerative medicine

As outlined above, Canada has been one of the leading nations in regenerative medicine and some of the most important discoveries in this field were made by Canadian scientists[10]. As such, there is a huge potential for the development of new commercially successful products in this area. However, in spite of the worldwide renowned expertise of Canadian scientists in Regenerative Medicine basic research, at present only a few products are under development by only a very few Canadian companies in this area. Over the past few years, this has triggered enormous efforts by the Canadian Government, to facilitate the commercialization of Regenerative Medicine approaches in Canada by implementing appropriate funding programs. Part of this strategy also is to look worldwide for expertise in applied research and the successful commercialization of innovative technologies, which in turn has been the reason for the great interest on the Canadian side in establishing FPC in Canada. Thus, from a governmental and strategic point of view, a joint initiative of a Canadian academic institution with Fraunhofer will find broad support by Canadian funding agencies and will get access to enormous amounts of grants and other funding sources available in Canada.

From an industrial point of view, regenerative medicine and in particular cell-based therapies truly have the potential to become a disruptive technology that allows the development of therapies for serious diseases where currently no appropriate therapy exists. However, representing the third pillar of therapeutic approaches besides small organic molecules and biologicals, there are still significant problems and challenges associated with cell-based therapies that have hampered until now such therapeutic products from becoming true commercial success stories. There are two main problem categories:

First, some of the cell-based therapies currently in late stage development or already on the market obviously are facing issues related to their therapeutic efficiency. A cell-based therapeutic approach certainly is even more complicated with regard to its mode of action than many other "old-fashioned" standard approaches and in some cases, important cellular signalling and modulation pathways have not been understood well enough to create highly efficient therapeutic options. There is a vast research and development need in this area in order to create new therapies featuring the expected high level of therapeutic efficiency. Thus, many cell therapy companies are very much interested in getting access to new and innovative cell-based therapies.

Second, almost all of the currently marketed cell-based therapies are facing the issue of being by far too expensive to be acceptable for public health systems. This is mainly due to the fact that currently established manufacturing processes still involve many hands-on steps and are far from being automated. All of the process automation steps that helped, decades and/or centuries ago, to make the manufacturing of tablets and injectable biologicals solutions cost-efficient still cannot be done in this quite young area. Thus, there is a huge need to develop and implement automation solutions for the manufacturing of already developed cell-based therapies. Almost all cell therapy companies are very much interested in the development of such automated manufacturing processes as this will be the only chance for them to achieve a cost structure for their therapeutics that allows, on mid and long term view, reimbursement by public health organizations in the developed countries worldwide.

As already introduced in section 5.1 (market overview) there are many regenerative medicine companies in the Greater Toronto Area including Hamilton and Mississauga (GTA) as well as in the adjacent regions of the United States. All large biotech clusters in Northeast America including Montreal, Ottawa, Boston, New York, New Haven, in Rhode Island, New Jersey and Chicago are in reach within 45 flight minutes from Toronto Pearson's international airport. All of these companies represent a rich customer base for joint development and/or contract research projects dealing with the development of new cell therapeutic approaches and/or automation solutions for their cost-efficient manufacturing.

6.3 Business model in detail

As previously outlined FPC will focus on business models that will carry out activities such as:

- joint development projects with industry partners
- contract research for industry partners
- publicly funded research and commercialization of resulting IPR and technologies

In practice, particular projects are expected to be performed as a mixture of these basic collaboration types. For example, the Canadian Federal and Province Governments may provide matching funds that can be used to leverage industry-funded joint development projects, leading to a mixed model of industry-driven development projects and publicly funded applied research.

Moreover, the type of business model applied depends first of all on the demand from the client, the options offered by a certain technology area covered, the available IP existing or created at FPC and also on the availability of public funding options. In general, ownership, access rights, protection and commercialization of IP is governed by the "Framework for a Joint Initiative" Agreement between Fraunhofer and McMaster. IP developed as a result of research within FPC will be jointly owned by McMaster and Fraunhofer. It will be defined in each individual case, whether Fraunhofer or McMaster is to take the lead for filing, protection, and maintenance of IP, as well as commercialization for the joint benefit. This is the case in both publically funded, joint development and contract research projects.

A main difference between joint development projects and contract research projects is the question of how resulting IP from the project will be managed between McMaster / Fraunhofer and the industry client as a third party. As stated above, IP arising from such projects is also covered by the "Framework for a Joint Initiative" Agreement. McMaster and Fraunhofer intend to retain IP ownership, and then to grant licenses to the client. Royalties or other commercialization revenues will be returned to FPC and shared between McMaster and Fraunhofer. This option certainly will be preferred as it generates more sustainable revenues for the FPC and helps to generate a valuable IPR portfolio for FPC. Thus, this model will be applied to large development programmes with industry partners where FPC contributes its own background IP. From a technology point of view, this model will apply, just for example, to large projects dealing with the joint development of new cell therapies and entire manufacturing automation solutions.

As it may be confusing for partners and clients to have either McMaster or Fraunhofer in the lead with different IP, all communication with external partners and clients, public or private, shall be executed via FPC and governed by the FPC directorate.

Contract research projects usually are smaller than joint development projects and focus on service-related models (e.g. testing of a therapeutic substance provided by the client in a different field of application) in which a limited number of working steps with a very clear and limited goal is given by the client, and de novo generation of IP is not likely. Usually, the volume of such contract research projects will be limited compared to the large joint development projects. However, they can be set up faster than joint development projects and very often serve as an entry point for industry customers. For example, it is expected that a company client may start interactions with FPC via a small contract research project to test the waters, and then continue (after completion of the first contract and analyses of the quality and quantity of the results) with larger joint development projects. Thus, from FPC´s point of view, such contract research projects are of utmost value for FPC even though their financial volume might be limited and all IP associated directly with the ordered subject (e.g. a drug candidate to be tested) will presumably belong to the client.

In the event of commercialization from licensing of IP, the royalties and revenues generated will be shared between McMaster (FPC) and Fraunhofer. The distribution of such commercialization revenues shall be shared between the parties on the basis of the "Framework for a Joint Initiative" Agreement. If FPC is successful as envisioned, the FPC management team will decide further research activities to enable the sustainability and growth of FPC.

6.4 Targeted business areas, customers and branches

The FPC will become active in the areas of highly innovative cell therapy products and GMP grade, automated cell production. While both areas are essentially linked, approaches to generate novel IP and a sound commercialization perspective differ significantly between the areas. Pilot projects being exemplary for the research in these areas have been introduced in **chapter 2.2**.

6.5 Scope on customers I: innovative cell therapy for regenerative medicine

This business area comprises aspects of biomedical engineering (the "BE" in BEAM) to robustly and safely modify or generate stem and immune cell populations as therapeutic agents or cellular vaccines. Next to this, patient-specific pluripotent cells can be used for diagnostic purposes when derived

from a patient: they can mimic a pathophysiological phenotype of diseases with genetic influences *in vitro*. The field also comprises strategies to modulate responses of immune cell population to enhance endogenous repair mechanisms or to ameliorate "collateral" immune damage during diseases. McMaster and IZI scientists have developed a number of promising concepts for such cell-based approaches, including concepts to ameliorate damage after acute and chronic neurological injury, which are expected to be ready for commercialization within two to four years. This is because IP for innovative cell therapy products emerges from fundamental research with a clear application perspective (publically funded) which, subsequently, will need to be performed at FPC. After preclinical assessment of these novel strategies including sound safety and efficacy studies, the products are ready to be offered to industrial partners either before (faster and cheaper, but lower ROI) or after initial stage clinical trials (more time- and resource-consuming, but potential higher ROI). Although clinical trials will not be within the scope of FPC, it can take advantage of the McMaster medical infrastructure and clinical partners of Fraunhofer IZI if needed.

Potential customers for developed therapeutic cell products are large scale health care providers or, primarily, the globally active pharmaceutical industry. Commercialization shall mainly be conducted by negotiating licences. Next to this, FPC can become active as a contract research partner developing, assessing, improving or implementing novel cell therapies for a customer community comprised of small and medium-sized enterprises. The clear demand in the field is outlined by the market survey in **chapter 5**.

6.6 Scope on customers II: automated cell production and diagnostics

Nowadays, therapeutic cell products are manufactured under GMP conditions by specially trained professionals in a clean room environment in individual, manual operation steps using standard laboratory equipment. While this approach is feasible to produce high quality cell products, the "human factor" may still cause inter-batch variations and, more severely, the number of output cell products is limited. This is fine for ongoing small scale clinical trials. However, transforming cell therapies into a routine clinical procedure will require much larger product numbers and hence specialized cell factories rather than manufactories. Automated engineering (the "AM" in BEAM) business strategy means that the centre will take advantage of both, the vast GMP experience at Fraunhofer IZI and the automation expertise of McMaster biomedical engineers. Automated cell production will also call for automated quality management and control, particularly the surveillance of crucial production steps. This will require, lab-scale, highly specialized diagnostic modules capable of monitoring

production steps. Both partners will combine their unique expertise to develop and implement such tools.

Revenues in this will be generated mainly in form of technology licences. Customers will be public and private GMP manufacturers willing to be among the pioneers of next generation GMP-grade cell manufacturing. A pilot workshop on automated GMP production jointly organized by McMaster and Fraunhofer IZI in April 2014 has attracted by far more industrial delegates than originally anticipated, underlining the clear demand for such technologies.

6.7 Scope on customers III: Point of care diagnostics

Next to their utilization as monitoring instruments, the diagnostic technologies developed at FPC clearly exhibit the potential of becoming a highly interesting, independent product line. FPC, which also unites professional expertise in the field of diagnostics by its Canadian and German partners, sees promising potential, particularly in the field of POC diagnostics. These are cost effective, mobile (or even home-care) diagnostic solutions for a relatively broad use. The "classical" POC application is glucose screening which became a central element of blood glucose management in diabetics worldwide. In contrast to highly automated, complex and centralized diagnostic centers, POC diagnostics are optimized for accuracy and robustness while tailored to a certain, specific application. This allows a broad easy utilization of these diagnostics. Other fields may comprise detection of infectious agents. Central elements of POC development will be the implementation of novel and cost-effective sensor technologies and sample-processing technology on the POC diagnostic equipment (see **project example 6**). Requiring a certain level of automation, a clear link is given to the "advanced manufacturing" field.

It is expected that the diagnostic developments, for example pursued as monitoring instruments in the automated production focus of FPC, will lead to secondary, but not minor, utilization in related fields, such as lab-on-a-chip, mobile and bedside diagnostics. Next to this, FPC will also focus on the developments which claim POC diagnostic solutions as the primary research and development endpoint. Customers will benefit from ready-to-use solutions which can be easily implemented in their product portfolio. The implementation of single-use, disposable components for the POC systems enhances commercial attractiveness for industry partners.

Hence, a number of companies being active in the field of diagnostics have expressed their strong interest to collaborate with FPC in this field (see **Table 1**).

6.8 Other customers, services and business models

Next to this FPC will also serve as an implementation and service hub for the biomedical industry. Particularly, it will house representatives and/or machinery of European (e.g. German) small and medium-sized biotech companies willing to explore the North American market.

Equipment can be displayed in specialized show rooms or "glass laboratories" where they can be presented to an external audience. This allows the development of a presence at the regional market with a comparatively small budget. This business model clearly has a short-term service component, but its long-term goal is to implement these customer's technologies to one of the two main business areas pursued at FPC. The spectrum of interested partner companies clearly implies that they have a close relation to one or both areas. Hence, this option can clearly be considered as a starting option to partner up with FPC specialists for additional projects. Show rooms may also be occupied by other Fraunhofer institutes intending to introduce their achievements to the North American market more aggressively.

6.9 Potential customers from the private sector

As soon as the word spread that McMaster University and Fraunhofer IZI were planning to start a joint project centre, a number of companies from Canada and Germany have expressed their strong interest and, to some extent, precise commitments to this upcoming centre even though it has not yet materialized by a formal decision (see **Appendix D1**).

Company	Expertise/Field
Companies based in North America	
Argos Therapeutics Inc.	Cell Therapy
BioSpherix Ltd.	Equipment for Cell Therapy
Bruker Ltd.	Diagnostics
Lumira Capital[1]	Venture Capital and Cell Therapy
PCT Cell Therapy Services	Cell Therapy
PerkinElmer	Diagnostics
Pro-Lab Diagnostics	Diagnostics
Safeguard Biosystems Inc.	Diagnostics
Companies based in Germany	
ALS Automated Lab Solutions GmbH	Cell biology and molecular biology
Partec GmbH	Medical diagnostics
Vita 34 AG	Cell therapy
Microfluidic ChipShop GmbH	Diagnostics
Tutelacell GmbH	Consulting
Prima BioMed GmbH	Cell Therapy

Table 1: Overview of companies interested in FPC activities

Further potential companies and customers close to FPC are listed in **Appendix D2**.

7 Implementation

7.1 Organization and FPC management

7.1.1 Organizational Structure

The partners envision establishing a jointly managed structure of FPC at McMaster University. Fraunhofer is expected to permit using the name "Fraunhofer" for this structure after reviewing the business plan in August 2014. Fraunhofer is further expected to agree that the Fraunhofer IZI operates this structure at and together with McMaster University.

FPC will be the created pursuant and be subject to the University's applicable policy: Guidelines for the Governance and Review of Research Institutes, Centres and Groups as well as pursuant to frame work contract negotiated between McM and Fraunhofer.

Further details will be fixed by a framework agreement which will form the legal contract between Fraunhofer and McMaster comprising all obligations, commitments, reporting mechanisms, rights as well as any other legally relevant aspect of the collaboration.

FPC will be steered by a double directorate (see **Figure 4**) being supported by two assistant directors, ideally reflecting the close collaborative approach. Given the envisioned impact of FPC activities on a broad spectrum of scientific and business areas, a double leadership will enable FPC to cover a broader spectrum of domain-specific expertise within the senior management. Also, this structure will help to utilize industrial contacts on both sides of the Atlantic.

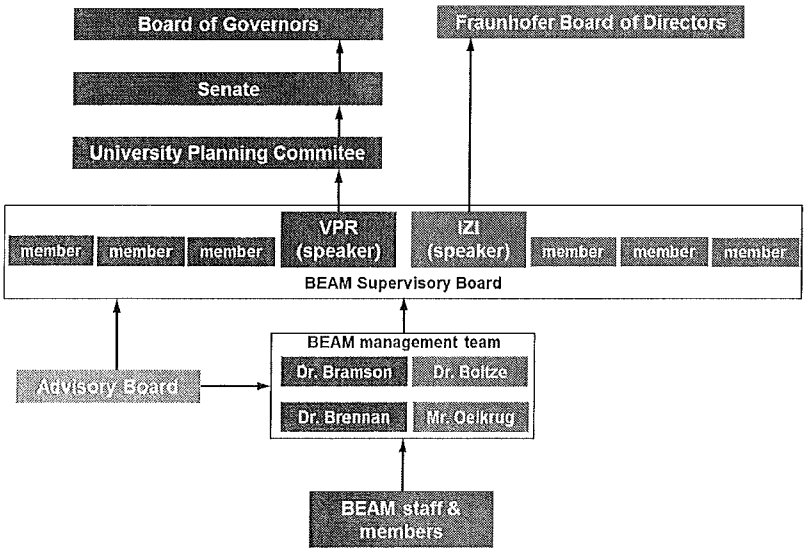


Figure 4: Organizational Structure of FPC at McMaster University in cooperation with Fraunhofer IZI.

Dr. Mo Elbestawi, Vice president of Research at McM and Dr. Frank Emmrich, Head of Fraunhofer IZI will serve as the inaugural board speakers and will be responsible for reporting to McM and Fraunhofer superiorities, respectively. Besides directing Fraunhofer IZI, Dr. Emmrich is full professor of Clinical Immunology and director of the Translational Centre for Regenerative Medicine at the University of Leipzig. The latter has been funded with €70.0 M by the Federal and Saxonian Government since 2006.

Both parties recognize the importance of these positions for the success of the joint project centre and have identified key personnel to cover these positions. McMaster will nominate Dr. Jonathan Bramson, PhD, who is a full professor of immunology at McMaster University as the inaugural FPC director. Dr. Bramson holds the Canada Research Chair in Translational Cancer Immunology and the Bienenstock Chair in Molecular Medicine. He is the Director of the McMaster Immunology Research Centre, which is home to 12 individual research labs and 146 research staff. He brings strong leadership skills to FPC and extensive experience in the areas of cell therapy and cancer immunotherapy. The assistant FPC director from McMaster University will be Dr. John Brennan, PhD. Dr. Brennan is a full professor and holds the Canada Research Chair in Bioanalytical Chemistry and Biointerfaces. He is the founding Director of the Biointerfaces Institute, which consists of 25 core and associate members and over 150 research personnel, and currently manages an academic group of 25 researchers, many of whom work on applied projects that are sponsored by local industrial partners. He brings substantial expertise in the area of POC diagnostics and materials development to FPC.

Fraunhofer IZI has identified Dr. Johannes Boltze, MD, PhD as the inaugural FPC director nominated from its side. Dr. Boltze has profound expertise in experimental neurology and neurosurgery, particularly in the field of stem cell therapies. Dr. Boltze will become an adjunct faculty member of McMaster University, thereby being legally enabled to act as a FPC director. The same holds true for Christopher Oelkrug, M.Sc. (Cancer Immunology and Biotechnology) assistant FPC director to be nominated by Fraunhofer IZI. He heads the Immunotherapy/Oncology group at Fraunhofer IZI and therefore brings profound expertise matching FPC's core business areas. He is also a native German-Canadian with close relatives living near Hamilton, so he is very familiar with the administrative, academic and business environment in Southern Ontario. To secure an optimal start of FPC, either the German director or the assistant director will be present in Hamilton for most of the year during the initial three years. However, time of residency will not exceed 183 days annually for each scientist.

7.1.2 FPC Governance

Both FPC directors and their respective assistants are responsible for the daily management of the Project Centre. The directors will coordinate and decide on planning and budgeting, the scientific strategy, allocation of resources to business areas, securing of intellectual property, contract negotiations (together with legal representatives, if demanded), fund raising, quality control, and staff organization (internal management). Responsibilities to be allocated among the FPC directors include:

- recommending any new advisors to add to the industrial advisory board
- recommending any new potential industry partners
- recruiting staff
- supervising FPC personnel
- overseeing the preparation of financial and other reports
- overseeing communications and public affairs
- overseeing the planning, development and management of FPC space
- overseeing the organization of quarterly FPC staff and other meetings

They will also be responsible for creating FPC awareness with industry and academic partners, as well as representatives from the local and federal government, and to build up the FPC North American network (external management). This will include:

- liaising with government and granting bodies regarding funding
- communicating and promoting FPC's objectives and activities to the research community and private and public sector organizations

Signatures of both directors will be required to commit FPC as in-house-unit of McM to any substantial scientific, structural, management or material decision. Dr. Boltze and Mr. Oelkrug will receive part-time faculty status at McMaster University.

The directors will be supported by a business development manager and a secretary (positions allocated to FPC by McMaster), as well as the two assistant directors (see **Figure 4**). In case one of the directors is not

present at FPC, the assistant director will be responsible for immediate decisions not allowing postponement.

The directors, or their respective deputies, manage the day-to-day business. To this end, they will define internal rules of operation and orders which control all relevant decision making procedures. In the unexpected case that the directors cannot agree on a certain decision regarding a pivotal subject, the case may be forwarded to the Supervisory Board (see **Figure 4**).

Both Fraunhofer directors will have the same signing authority as the McM directors. However, this does not include the ability to sign contracts with industrial partners or sign on behalf of McM for submitting grant proposals, but authorized representatives of McMaster's central administrations need to sign on behalf of FPC.

For the purposes of the grant applications, signatures are required from the PI(s), Chair, Dean, and Director of the appropriate research administration office (VP Research delegate).

For the purposes of the research contracts with an industry partner and other legal agreements dealing with intellectual property, the workflow is that the agreements would be reviewed by the appropriate research administration office at McM (either MILO, ROADS, HRS) and the authorized signatory for McMaster would be the director of that office; unless the agreement cash value is over $2.0M CAD, in which case it would need two signatures from the Associate VP or VP level (usually VP Research and VP Administration).

Once a grant or research contract is in place, then the PIs (the four directors) would have signing authority on the account, and so would be able to sign for purchases and use of funds in accordance with the approved budget.

Together with the FPC directors, the assistant directors will file semi-annual reports to the Supervisory Board no later than June 15th and November 30th. These reports will comprise a comprehensive summary of all activities, a budgetary report as well as a success assessment in relation to pre-set financial and scientific aims to ensure FPC success criteria for evaluation (see **chapter 9.5**) will be met.

7.1.3 Supervisory board

The FPC Supervisory board (see **Figure 4**) shall consist of four representatives each from McMaster and Fraunhofer. McMaster intends to nominate the Vice President Research (VPR) and the Deans of Health Sciences, Engineering and Science as members of the governing board.

Fraunhofer will suggest senior Fraunhofer IZI and Fraunhofer head-quarter managers as Supervisory Board members.
McMaster and Fraunhofer representatives in the Supervisory Board will elect a speaker for either side. The Fraunhofer Society intends to nominate Professor Frank Emmrich as the speaker while McMaster University will nominate Dr. Mo Elbestawi (VPR) as the speaker. Speakers will alternate leading the governing board for one year each. Both speakers will report to their institutional authorities as given by **Figure 4**.

The Supervisory Board will meet at least once a year in person, preferentially to discuss the report issued after the end of the financial year of McMaster (end of April) around June 15th.They will review the semi-annual reports by the FPC management team, provide substantial feedback and will also suggest potential amendments in business and scientific strategies for the upcoming year to ensure the FPC evaluation success criteria will be met.

7.1.4 Advisory board

A group of industrial and academic leaders in the fields of cell therapy and GMP cell production will be formed by up to nine representatives from prominent companies and universities in these sectors (6 industrial and 3 academic leaders).

This group is expected to consult the FPC management team as well as the Supervisory Board regarding its research strategy by outlining present and anticipated industrial demands, the FPC business as well as commercialization strategy. The advisory board members are also expected to amend the FPC awareness among other industrial representatives or may act as FPC advocates/references during important negotiations with the industry and academic partners/customers.

Advisory board candidates will be nominated jointly by the FPC management team and the Supervisory board. Board members shall be elected to the board for three years (can be extended on request). The industrial advisory board is expected to nominate a speaker. The FPC management team and the FPC supervisory board can call the board for advice and will invite the Board for at least one joint meeting per year, during which the semi-annual reports will also be discussed.

7.2 Measures to support FPC research and commercialization

Next to the joint centre management and governance structure, FPC and IZI will establish instruments fostering a close collaboration between both institutions to facilitate close-to market R&D projects, fundraising activities

and joint attraction of partners and customers. Cornerstones of these programs are outlined in **chapter 8**, for staff planning please refer to **9.3**.

8 Transatlantic collaboration between FPC and Fraunhofer IZI

The FPC management envisions a close collaboration between key personnel at McMaster University and Fraunhofer IZI. Next to the continuous exchange and joint administration of the project centre by the managing and deputy directors as outlined in **chapter 7.1**, a number of activities are planned to ensure a close collaboration and a continuous FPC success. The activities are specified by the following paragraphs and detailed financial figures are given in **chapter 10**.

8.1 Joint technology developments and close-to-market R&D projects

As outlined before, FPC will be an institution governed according to the rules of the McMaster University. It will, however, pursue relevant findings obtained in both institutions with the aim to unite their expertise in order to create highly innovative products and technologies for timely market introduction. To this end, the FPC staff covered by public and industry projects will be reinforced by McMaster and IZI personnel from the beginning.

8.2 Staff allocation to FPC by McMaster University

Immediately after the FPC establishment, McM will allocate full time equivalents (FTEs; scientist and technicians) to FPC for a period of 5 years. The FPC directors will agree on allocation of the staff to particular promising R&D projects or important industrial contract research activities requiring additional manpower. McMaster University will also hire a business development manager and a secretary to support the FPC management team. Further, a footprint of 40,000 sq ft has been assigned to FPC for initial activity and future expansion. Value of this space is estimated at $4.0M CAD, and is a part of McMaster's contribution towards construction of the FPC facility.

8.3 "Mirror" (IZI) research positions, consumables and mobility programmes

The Fraunhofer Society and IZI will combine intramural funds to support the FPC setup and launch, joint product development and collaboration. This is

called the **"Incentive Startup Grant" program.** The programme contains so called "mirror" positions, a reasonable budget for consumables, as well as mobility options. Access to these resources will be granted by an IZI research programme review committee headed by the German FPC director, who will also control the allocation and use. All three options can be combined, if appropriate. A core criterion for granting applications will be the additional value of the proposed activity, which must clearly contribute to activities filling the FPC product pipeline, supporting highly important FPC projects demanding support, or finalizing/optimizing FPC products.

"Mirror" positions: At Fraunhofer IZI, three to seven positions for staff scientists and/or technicians will be created and travel funds will be allocated. Fraunhofer IZI will identify synergies in intramural research programmes corresponding to FPC activities. Groups running synergistic programmes and intending to contribute to such FPC activities may apply to receive one of these positions which must be entirely dedicated to FPC research activities.

Personnel covered by mirror positions are intended to actively collaborate with Canadian colleagues on site and to take advantage of their unique position to raise additional third party funding. These activities can be supported by mobility programmes (see below), but IZI personnel will typically stay at FPC two to three months annually. Research stays will not exceed 6 months (180 days).

Consumables: Fraunhofer research groups can also apply for consumables covering FPC-related research activities.

Mobility grants: Mobility funds will be available to cover travel expenses of IZI scientists intending to collaborate with FPC colleagues on projects being relevant to the centre.

8.3.1 Mutual support for exchange personnel

Fraunhofer IZI and McMaster University will support exchange staff working at the partner's institution. This may include appointments as guest/visiting scientists, assistance in administrative issues, apartment search and familiarization events. An "integration plan" will be finalized before staff is exchanged.

8.3.2 In-kind contribution and support

Fraunhofer IZI will allocate pre-processed material (e.g. stem cell lines), licences, know how or particular services to FPC. The full range of Fraunhofer expertise is available to support FPC projects with in kind material and personnel being paid by Fraunhofer, but not being part of FPC.

Moreover, graduate students who may significantly contribute to FPC activities may work for those while working at IZI without being covered by above mentioned collaboration funds. In this case, working time and resources will be acknowledged as in-kind support as well. The annual amount of in-kind contributions being available for FPC and its activities will be at least $200,000 CAD and is expected to average at $500,000 CAD annually. In-kind contributions can be used by FPC to leverage particularly public (e.g. Ontario Research Fund, ORF) contributions to FPC.

8.3.3 Joint fundraising and subcontracting activities

The FPC management team will utilize opportunities for public and industrial fundraising in North America, Germany, and Europe. Personnel exchange programmes and the double directorship supports these endeavors. Where appropriate, centres may subcontract each other, tax ruling permitting. For example, the FPC will subcontract Fraunhofer IZI for specialized project work packages that can be performed best at Fraunhofer IZI and/or are required to attract a certain customer to FPC.

8.3.4 Joint scientific symposia

FPC and Fraunhofer IZI will organize an annual workshop on automation of GMP cell production. The workshop will bring together academic and industry leaders from the field to discuss future trends and demands in the field. Next to the exchange of ideas and learning more about the industrial demands, the workshop may serve as an ideal marketing platform as FPC products and technologies will be introduced to a broader customer and partner community. McMaster University and IZI have organized a first pilot workshop (**Appendix G**) in April 2014, which was an overwhelming success.

Therapeutic cell products and innovative treatment concepts, rather than GMP production and automation technologies, will be presented and discussed with customers at the Fraunhofer Life Science Symposium and the World Congress of Regenerative Medicine both being organized by the Fraunhofer IZI in Leipzig, with McMaster and FPC colleagues contributing as members of the scientific and organizational meeting boards and key note speakers.

8.3.5 Communication and reporting

There will be a continuous communication between the FPC management team members. They will file reports to the Supervisory Board semi-annually or on request. For details, please refer to **chapter 7**.

Research teams at FPC, regardless of their composition of McMaster and IZI colleagues, will have weekly project meetings to be organized by the respective research team leader. In case teams are composed of members working at FPC and IZI simultaneously, there will be at least one Skype and/or telephone conference per month. Moreover, FPC research groups will file formal, quarterly reports to the FPC management. "Mirror" (IZI) personnel will transfer these reports to the responsible IZI department heads. All meetings will be subject to written documentation of key results and decisions.

9 Marketing of offered services and results

The FPC management team and the associated business development officer will be responsible to create awareness of FPC capabilities and activities among customers and partners and closely collaborate with the established Business Development departments at Fraunhofer IZI and McMaster University. Initially, the foundation of FPC as well as the full spectrum of its initial and future competencies will be announced at large scale fairs (e.g. the BIO, including its regional activities in Europe and North America) as well as on scientific symposia.

A marketing plan will be executed as soon as products and services are ready to be offered and transitory FPC facilities are operational (expected for fall 2014). Here, three different stages can be discriminated, which will call for different marketing activities.

9.1.1 FPC startup (08/2014-03/2016)

The initial phase is characterized by limited availability of lab and office space in Hamilton (transitory FPC facilities). The FPC will be housed transiently by MIRC at McMaster and the number of projects to be conducted at the space allocated to FPC is limited. Since both partners can backup FPC by their respective own facilities if needed, marketing can nevertheless be aggressive. FPC will begin to offer first results of its R&D activities to interested customers, being contacted by personal networks and the joint GMP production symposium. Partnering will focus on companies that are interested or capable in bringing additional value or resources to the FPC activities. To ensure success at this stage, sole contract research activities will be given lower priority in case no capacity is available at FPC, McMaster or Fraunhofer IZI which, however, is not expected to be a frequent occurrence. The management team will make small and medium-sized companies aware of the service/representation that is available during the FPC growth phase (see below). FPC will also announce other McMaster / Fraunhofer IZI expertise to potential customers in case a need is recognized. FPC personnel can ideally support this with special competence required for such projects, bringing additional money to the centre.

9.1.2 FPC growth (04/2016-12/2018)

Starting with the move of FPC to its stationary building at McMaster Innovation Park, the centre's capacities will significantly grow. Results being

obtained during the original, mainly publically funded research stage will be commercialized and new partners will be attracted to the centre. This will be done by representation at fairs, personal networks, through workshops and publications and, if further stimulation on regional markets is demanded, by road shows throughout Eastern North America. During this phase, the business development team will be reinforced and the management team will more extensively focus on broad marketing activities. At the same time, European (e.g.) German companies will be attracted to FPC with the now available show and display rooms as well as the service for establishing a market presence in North America.

9.1.3 FPC full market penetration (01/2019 and beyond)

If final success evaluation criteria will be met in 03/2019 (6 months before the end of the initial 5-year turn), FPC will be ready to commercialize its results on addressed markets in Europe and North America. During this phase, the business development and service team may be reinforced to secure optimal customer relations. Significant expansion of FPC as a service and commercialization centre is expected during this time, so further capacities may be generated by increasing the FPC area, utilizing reserve space in the FPC building at the McMaster innovation park. Revenues will be used to further increase FPC activities on the addressed business areas or related once being identified as future emerging markets at this time.

9.2 Decision making and leadership in marketing

Leadership and governance of all FPC management processes have been described in previous chapters. In case of IP commercialization, partners will benefit from royalties and revenues based on IP shares of the particular patents enrolled. If FPC is successful as envisioned, the management team will decide on further research activities as outlined for the FPC full market penetration phase.

9.3 Human resources planning

Table 2: Human resources planning for FPC (McM / IZI). *The table reflects FTE numbers given in the budget overview (Table 6).*

Staff category	Year 1 (05/2014 – 04/2015)		Year 2 (05/2015 – 04/2016)		Year 3 (05/2016 – 04/2017)		Year 4 (05/2017 – 04/2018)		Year 5 (05/2018 – 04/2019)	
	McM	IZI	McM	IZI	McM	IZI	McM	IZI	McM	IZI
Category A: Management and administration										
Managing directors	1	0.8*	1	0.8*	1	0.6*	1	0.5*	1	0.3*
Assistant directors	1	1	1	1	1	0.8	1	0.75	1	0.5
business development manager	1	0	1	0	1	0	1	0	1	0
secretary	0.4	0	0.4	0	1	0	1	0	1	0
Category B: Scientists and graduate students										
Scientists / post-doctoral fellow	0	1	2	1	10	1	15	1	15	1
Graduate students**	0	2	2	2	10	0	15	0	15	0
Category C: Technicians										
Senior technician / lab manager	0.4	0	0.4	0	1	0	1	1	1	1
technician	6	1	8	1	8	1	10	0	10	0
Category D: other IZI personnel										
Visiting scientists / Undergraduate students***	-	0 / 2	-	1 / 3	-	2 / 4	-	3 / 4	-	3 / 4
Total	**9.8**	**7.8**	**15.8**	**9.8**	**33.0**	**9.4**	**45.0**	**9.25**	**45.0**	**9.8**

Numbers give personnel as following: McM personnel / IZI personnel. Numbers represent full time equivalents. Numbers include personnel covered by intramural funds and external projects. Guest researchers or employees from academic or industrial partners being physically present in Hamilton/at FPC are not taken into consideration.

IZI personnel will work on subcontracts from FPC projects and may transiently reallocate to Canada to support research activities on site. This will not exceed 180 days (183 for directors) per person and year for taxation reasons and will be organized in a way that these activities are not subject to secondment rules in the German Public Service.

* Director's / IZI assistant director's positions will be partly covered by strategic research projects granted to FPC as it moves along. IZI management staff will also work for FPC when present in Germany. One IZI manager is always present in Hamilton at least for the initial three years.
** an IZI graduate student is 0.5 scientist's FTE
*** undergraduate students (including budget for consumables) provided by IZI will not be part of the FPC budget, but will be considered in-kind-support to ORF and other grants; Visiting scientists from IZI which are not part of FPC can transiently support FPC on site if beneficial for its activities. Those are considered in-kind-contributions as well.

9.4 Tasks and milestones

Table 3: Milestones for FPC development including responsibilities

Milestone	Timepoint	Comment	Responsibility
Future management teams, McM / Fraunhofer leaders work on the FPC concept and the business plan	01 – 04/2014	none	Management team
Business plan finalized and submitted	06/2014	none	Management team
Decision by Fraunhofer Board of Directors	08/2014	business plan approved, framework agreement negotiated and agreed upon in most crucial issues	Board of Directors
Framework agreement negotiated, closed and signed	08/2014	to be negotiated in parallel to business plan evaluation process by Fraunhofer Board of Directors	McM and Fraunhofer legal representatives
Management team is inaugurated	08/2014	after FhG Board decision	McM / Fraunhofer
FPC starts officially, first (internal) projects implemented	09/2014	solemn joint opening ceremony, Framework agreement is officially signed	Management team
First ORF grants completed and submitted	07/2014	under preparation since 01/2014	Management team
Transitional phase FPC facility operational, first visiting scientists arrive to FPC	10/2014	none	Management team
Project acquisition for FPC starts	10/2014	none	Management team
Construction schedule for FPC stationary phase* finalized with McMaster officials (*Stationary phase refers to FPC at its permanent space at MIP)	01/2015	none	Management team and responsible McM officers
First external project granted to FPC	02/2015	none	Management team
Hiring of transitional phase personnel completed	03/2015	some reserve time included as highly qualified staff may not be available on demand	Management team
Construction for FPC stationary phase* starts	03/2015	none	Responsible McM officers
External project volume attracted to FPC exceeds $1.5 M CAD	03/2016	none	Management team
FPC review (1.5-year term)	03/2016	see suggested criteria	Management team
Submission of evaluation reports	04/2016	Filing of the evaluation reports	Management team
Review of evaluation reports and decision	06/2016	Referee team meeting 15th June	Referee team
Completion of FPC stationary phase	03/2016	none	Construction teams/ McM officers
External project volume attracted to FPC exceeds $2.0 M CAD	03/2016	none	Management team
Stationary phase completely operational	04/2016	all equipment delivered	Management team
First industry partner subsidiary on site at FPC	06/2016	none	Management team
Hiring for FPC stationary phase completed	10/2016	none	Management team
External project volume attracted to FPC exceeds $6.0 M CAD	03/2018	none	Management team
External project volume attracted to FPC exceeds $8.0 M CAD	03/2019	none	Management team
FPC review (4.5-year term)	03/2019	see suggested criteria	Management team
Submission of evaluation reports	04/2019	Filing of the evaluation reports	Management team
Review of evaluation reports and decision	06/2019	Referee team meeting 15th June	Referee team
Application for FPC continuation filed to Fraunhofer Board of Directors and McMaster University	07/2019	in case 4.5-year evaluation criteria were met	Management team

Decision on FPC continuation at Fraunhofer Board of Directors and McMaster University	09/2019	none	Fraunhofer Board of Directors / McM representatives

9.5 Success criteria for the evaluation of the first project phase

There will be two evaluation steps for FPC for which the achievement of predefined milestones as well as qualitative and quantitative scientific and business criteria will be evaluated till June 15th. The evaluation will be conducted by a referee team composed of Fraunhofer central administration and McM officials, but excluding the management team and members of the Supervisory Board. This might include site visits and discussions in Hamilton. The speakers of the Supervisory Board may act as consulting members of the review team on each side when they are required and asked to do so by their respective review team representatives. Basic information for the referee teams will be provided by the FPC management team. Reports will be issued to the referee team after McMaster's financial year (end of April) including the financial reports retroactive to March. (3/2016 and 3/2019)

The first evaluation period will be after 1.5 years (3/2016), mainly covering the FPC transitional phase. At this point, it will be clear whether FPC will meet the mid-term expectations as defined in this business plan. The assessment will also allow justification whether or not adjustment of the FPC strategy will be required and/or whether novel business fields may have been explored which should be addressed more aggressively within the next 3 years.

The thorough and strict 4.5 year (3/2019) evaluation will be in time to evaluate FPC's overall success before any decision about the continuation of the Project Centre will be made or a potential transition into a permanent Fraunhofer Centre will be contemplated. It is foreseen that it will comprise an onsite inspection of FPC facilities also by high-ranking Fraunhofer central administration officials.

9.5.1 Intermediate 1.5-year evaluation (3/2016)

After 1.5 years, FPC is expected to have raised $1.5 M CAD or more, mainly coming from public sources. This amount includes money obtained from leveraging sources, e.g. to backup industry contributions by public funds (a common model in Canada). Industrial contributions shall account for at least 25% of this volume or a minimum of $375,000 CAD. Fraunhofer shall participate on at least 2 sub-projects. Industrial partners may not have yet requested FPC representation as the stationary phase is operational for no more than 6 months at this point and time.

Table 4 represents the minimal target figures the Fraunhofer-Society is expecting as an ROI after 1.5 years (till 3/2016) of FPC operation. Hence, volumes are lower than those figured out in the overall budget estimation (**Table 6**), which provides a more optimistic scenario.

Table 4. Performance indicators for the 1.5-year evaluation

Category / Item	Quantity / Volume
Number of public projects granted to FPC	4
Number of industrial projects granted to FPC	4
Number of subprojects given to Fraunhofer IZI	2
Volume of project shares for Fraunhofer IZI from industrial projects	$100,000 CAD
Volume of project shares for Fraunhofer IZI from publically funded projects	$400,000 CAD
Total amount of industrial revenues at FPC	$375,000 CAD
Total amount of project revenues at FPC	$1.5 M CAD
Number of patents filed	2
Number of license negotiations with the industry	0 or 1
Number of scientific publications submitted	3
Number of participations at Biotech exhibitions (active partnering or booth)	3
Number of in-house workshops or conferences organized	1
Number of industrial partners present at FPC	0

In case the minimum target figures will not be reached, a thorough analysis will be conducted. Of particular importance will be figures concerning acquired industrial contributions to FPC (short- and mid-term success criterion) and filed patents (important for FPC long term success).

In case the minimum target figures for each of the financial targets reaches only 50% or less, but not the expected volumes, the Supervisory Board, together with the management team, will discuss measures how the FPC can make up for the delay in growth and effectiveness. This process may also consider recommendations of the Advisory Board and will result in thorough and strict, formalized reviews of upcoming semi-annual reports.

In case the volumes for any of the minimum target figures are only reached to less than 50%, the same measures will apply and, additionally, Fraunhofer support for the mirror group in Leipzig will be cut to 50% for the rest of the initial 5-year period.

9.5.2 Final 4.5-year evaluation (3/2019)

After 4.5 years, project revenues are expected to have significantly increased to at least $8.0 M CAD. This amount includes money obtained from leveraging sources, e.g. to backup industry contributions by public funds (a common model in Canada). A significant share of the income (at least 40% or $3.2 M CAD) shall come from the industry at this point. Fraunhofer IZI shall have participated in at least 8 sub-projects.

Next to this, a number of core patents will have been filed, some of which are in the process of being licenced to the industry. Stationary FPC will house representation units of 3 or more industry partners. Scientific publications, in-house workshops with significant industry

contribution as well as a continuous presence on exhibitions complete the FPC excellence portfolio.

Table 5 represents the minimal target figures the Fraunhofer-Society is expecting as an ROI after 4.5 years (till 3/2019) of FPC operation. Hence, volumes are lower than those figured out in the overall budget estimation (**Table 6**), which provides a more optimistic scenario.

Table 5. Performance indicators for the 4.5-year evaluation

Category / Item	Quantity / Volume
Number of public projects granted to FPC	9
Number of industrial projects granted to FPC	12
Number of subprojects given to Fraunhofer IZI	8
Volume of project shares for Fraunhofer IZI from industrial projects	$1.28 M CAD
Volume of project shares for Fraunhofer IZI from publically funded projects	$1.6 M CAD
Total amount of industrial revenues at FPC	$3.2 M CAD
Total amount of project revenues at FPC	$8.0+ M CAD
Number of patents filed	8
Number of licences negotiations with the industry	3
Number of scientific publications submitted	12
Number of participations at Biotech exhibitions (active partnering or both)	10
Number of in-house workshops or conferences organized	3
Number of industrial partners present at FPC	3

Meeting the performance indicators will be decisive for a positive evaluation of FPC. Based on the evaluation results, three scenarios are possible.

First, in case (**i**) all evaluation criteria will be met or exceeded, (**ii**) business opportunities for FPC and both partners continue to be growing and excellent, and (**iii**) both parties envision a continuation of the collaboration, they will then negotiate and agree on the terms and conditions for the continuation of the collaboration and the renewal of the framework agreement. Options for transforming FPC or parts of it into a Fraunhofer Centre may also be discussed, provided that the Fraunhofer Board of Directors agrees. In case a Fraunhofer Centre would be established, Fraunhofer-Gesellschaft would terminate the joint initiative in form of the Fraunhofer Project Centre and the new entity acting for a Fraunhofer Centre would enter into a new collaboration agreement with McMaster.

Second, in case the evaluation criteria regarding all financial target volumes are met to the amount of at least 75% and provided that both parties are willing to further collaborate, the framework agreement will be extended and FPC will be run for up to two additional years to see whether the evaluation criteria can finally be met before deciding on the future options as mentioned above.

Third, in case any of the financial criteria is not met appropriately (<75%) and/or at least one of the partners, Fraunhofer or McM, has reservations regarding the continuation of FPC in its present form, the centre activities may be terminated by 04/2019.

10 Costs and financing

10.1 Costs

Start-up costs for FPC infrastructure and Fraunhofer contribution

Stationary phase site
The anticipated FPC will be located at the McMaster Innovation Park's warehouse facility. McMaster will be providing a footprint of 40,000 sq ft to FPC, valued at $4M CAD, for initial activity and future expansion.

Fit Out Infrastructure Costs
Fitting out a leading edge, fully operational project centre beyond the structural skeleton with laboratory, office, meeting, storage and common spaces is estimated to cost $300 per square foot. In the first phase, we will fit out 20,000 sq ft at a cost of $6.0M CAD. The remaining 20,000 sq ft are an option to be completed as FPC's activities increase and require the additional space.

Fit Out Equipment Costs
Fitting out the FPC space with the appropriate equipment to fulfill its mission is estimated to cost $8.0 M CAD.

Initial operational costs for Fraunhofer (start-up financing only)
Initial operating costs (until the 1.5 year evaluation) for Fraunhofer are expected to be around €800,000 (€500,000 IZI + €300,000 Fraunhofer Central Funds) plus in-kind contributions (material, licences, technologies etc.), ranging between €200,000 and €500,000 annually. This does comprise any third public or industrial third party funds being raised during that time.

10.2 Start-up funding

Both McMaster and Fraunhofer Society are providing significant funding to the FPC initiative; however, full coverage of the costs of such an initiative is beyond the capabilities of the two institutions.

Given the transformative nature of the FPC initiative, funding from a wider range of sources has been requested including from industry partners as well as municipal, provincial and federal governments.

In addition, start-up construction and equipment funds have been raised, most of them being conditional to a positive decision by the

Fraunhofer Board of Directors, or will be raised immediately after that decision. These funds will be used according to **Figure 5**.

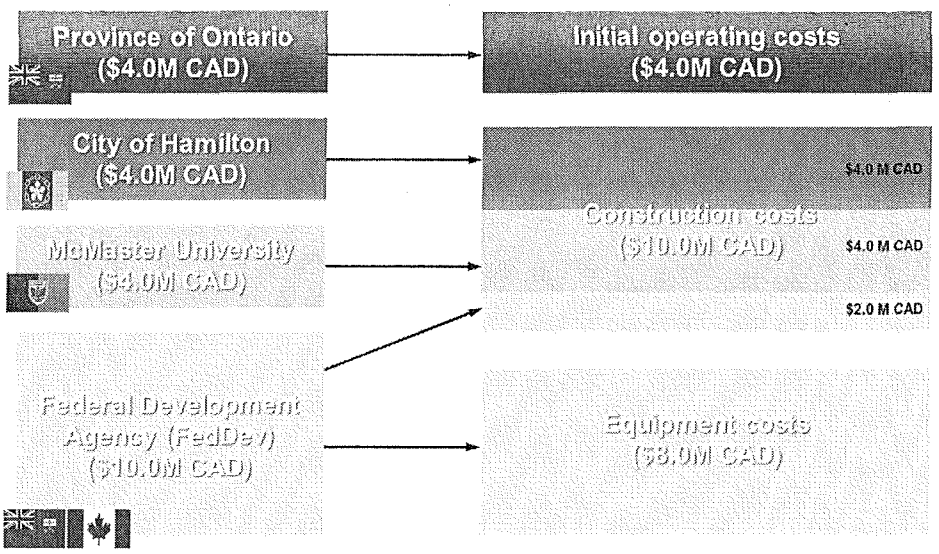


Figure 5: Utilization of start-up funds for FPC. Initial funds will be used as figured out by the chart. Bar width represents the volume of funds spent for the particular purpose. These figures do not include Fraunhofer funds supporting FPC in the 5-year turn. The start-up operational (project) costs covered from public sources will support FPC for no more than 4 years during this phase. These funds are already included in the "Public project funding" figures as given by the FPC budget overview (see chapter 10.3).

Start-up funding history (until 06/2014)

In April 2014, the Province of Ontario has already announced a total support of $4.0 M CAD for FPC for initial project costs in case the centre will be realized). Moreover, $4.0 M CAD will be available from the City of Hamilton for construction purposes, as confirmed by May 7th, 2014. McMaster will contribute another $4.0M CAD, valued as the land and building towards construction. All contributions are conditional to a positive decision of the Fraunhofer Board of Directors.

This package will be amended by an additional $10.0M CAD from Canadian federal sources for development (FED DEV; $2.0M CAD for construction and $8.0M CAD for equipment), cumulating to a start-up funding of $18.0 M CAD. These funds can be used for construction activities (stationary phase building), equipment and initial R&D activities according to **Figure 5**.

Fraunhofer has committed to provide funds of €1,750,000 (approx. $2.66M CAD) to support FPC activities during the five-year turn, providing a positive Statement of the Fraunhofer Board of Directors and provided that the financial targets at the intermediate evaluation are met as described in **chapter 10**. These funds will cover personal costs and the "mirror" group for support of FPC from the German side. Fraunhofer IZI will additionally contribute in-kind support.

A high level overview of the 5 year budget that includes the funds in **Figure 5** and **Table 6** is provided below.

High Level Overview of 5 year Budget

Use of Funds	Amount	Source
Stationary Site Preparation for FPC at MIP	$4M	McMaster – value of land and building (40,000 sq ft @ $100)
Architect and building permits	$1.6M	Province of Ontario
Construction / Renovations for 20,000 sq ft of FPC office and lab space (Phase 1)	$6M	Fed Dev, City of Hamilton
Large Equipment Costs for FPC manufacturing capabilities	$5M	Fed Dev
Operational Expenses for FPC	$18.9M	Industry contracts, Fraunhofer-IZI,Government grants, Province of Ontario, Fed Dev

Annual breakdown of Budget (estimated)

Year 1 – May 2014 to April 2015

Use of Funds	Amount	Source
Stationary Site Preparation for FPC at MIP	$4M	McMaster – value of land and building (40,000 sq ft @ $100)
Architect and building permits	$1.6M	Province of Ontario
Construction / Renovations to begin for 20,000 sq ft of FPC office and lab space	$2M	City of Hamilton
Operational Expenses for FPC at McMaster Campus (transition phase)	$800K + $1.07M	Industry contracts, Province of Ontario Fraunhofer IZI

Year 2 - May 2015 to April 2016

Use of Funds	Amount	Source
Construction / Renovations completed for 20,000 sq ft of FPC office and lab space	$4M	City of Hamilton, Fed Dev
Large Equipment Purchases for FPC Manufacturing	$3M	Fed Dev
Operational Expenses for FPC at McMaster campus until Dec. 2015 and MIP thereafter (stationary phase to start January 2016)	$1.89 $1.12M	Industry contracts, Province of Ontario, Fed Dev, government research grants Fraunhofer IZI

Year 3 - May 2016 to April 2017

Use of Funds	Amount	Source
Large Equipment Purchases for FPC Manufacturing	$2M	Fed Dev
Operational Expenses for FPC at MIP	$3.3M $806K	Industry contracts, Province of Ontario, Fed Dev, government research grants Fraunhofer IZI

Year 4 - May 2017 to April 2018

Use of Funds	Amount	Source
Operational Expenses for FPC at MIP	$4.22M $754K	Industry contracts, government research grants, commercialization revenues, Province of Ontario, Fed Dev Fraunhofer IZI

Year 5 - May 2018 to April 2019

Use of Funds	Amount	Source
Operational Expenses for FPC at MIP	$4.25M +	Industry contracts, government research grants, commercialization revenues, Province of Ontario, Fed Dev
	$655K	Fraunhofer IZI

This budget overview displays the proposed budget within the business plan, but commitments from Fraunhofer, McMaster, industry partners, and unconfirmed government grants may be revised. Furthermore, the Fraunhofer contribution may be reduced if the success criteria as outlined in the business plan are not achieved.

10.3 Operational budget, revenue planning and third party funding

The FPC overall operational budget is given in Table 6. The overview provides an estimation of the FPC budget over the entire 5-year turn, with industrial and public funding clearly being discriminable from Fraunhofer contributions. Both partners agree that Fraunhofer IZI will receive subcontracts from public and private projects given to FPC ("project shares"). Targeted project shares are 40% of each project to FPC to provide additional benefits for all FPC activities or 40% of the annual project volume. Since this will not possible with any individual projects (e.g. in publically funded projects or due to logistical or scientific restrictions), a conservative estimation is provided for shares of publically funded projects, which is 20%. In-kind support is not a part of the project calculation. Details regarding project share governance are provided by the Framework Agreement (**section IV. 4.**)

Table 6 provides a budgetary estimation based on more optimistic assumptions than those underlying **Tables 4 and 5** (providing minimal target figures), hence exhibiting larger financial volumes. Although ambitious, the FPC management team is optimistic that outlined dimensions can be met.

We foresee that FPC starts with minor cost under-absorption in the first year which will be compensated within the next 2.5 years before reaching a steady state. The expected revenues over 5 years are foreseen to exceed the costs by about $6,000 CAD over the entire 5-year turn. This small surplus shall be kept as a reserve, not a profit, to compensate unforeseen small-scale expenditures.

Table 6: BEAM operational budget, revenue planning and third party funding

FRAUNHOFER PROJECT CENTRE FOR BIOMEDICAL ENGINEERING AND ADVANCED MANUFACTURING AT McMASTER UNIVERSITY	Year 1 (May 2014-April 2015)		Year 2 (May 2015-April 2016)		Year 3 (May 2016-April 2017)		Year 4 (May 2017-April 2018)		Year 5 (May 2018-April 2019)	
FPC Operating Costs	**comments**	**McM**	**Fraunhofer**	**McM**	**Fraunhofer**	**McM**	**Fraunhofer**	**McM**	**Fraunhofer**	**McM**	**Fraunhofer**
Managing Directors: Dr. Bromson (McM), Dr. Balcao (IZI)	IZI: FTE: 0.8 / 0.9 / 0.8 / 0.5 / 0.3	$20,010.00	$200,275.20	$30,000.00	$202,449.41	$30,000.00	$154,135.80	$30,000.00	$135,370.40	$30,000.00	$78,222.24
Assistant Directors: Dr. Brennan (McM), Mr. Oelkrup (IZI)	IZI: FTE: 1.0 / 1.0 / 0.8 / 0.75 / 0.5	$20,010.00	$179,118.80	$30,000.00	$181,575.20	$30,000.00	$147,457.57	$30,000.00	$140,302.08	$30,000.00	$93,534.72
Business development manager	consultant	$120,000.00	$0.00	$150,000.00	$0.00	$150,000.00	$0.00	$150,000.00	$0.00	$150,000.00	$0.00
Secretary	FTE: 0.4 / 0.4 / 1 / 1 / 1	$17,342.00	$0.00	$26,783.00	$0.00	$68,953.00	$0.00	$68,958.00	$0.00	$68,959.00	$0.00
Post-doctoral research fellows / staff scientists	FTE: 0 / 2 / 10 / 15 / 15	$0.00	$0.00	$100,000.00	$0.00	$500,000.00	$0.00	$750,000.00	$0.00	$750,000.00	$0.00
Graduate students	FTE: 0 / 5 / 10 / 15 / 15	$0.00	$0.00	$42,200.00	$0.00	$120,000.00	$0.00	$180,000.00	$0.00	$180,000.00	$0.00
Undergraduate students (Fraunhofer in kind)	IZI FTE: 2 / 3 / 4 / 4 / 5	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Visiting scientists (Fraunhofer in kind)	IZI FTE: 0 / 1 / 2 / 3 / 3	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Senior technicians/lab managers	FTE: 0.4 / 0.4 / 1 / 1 / 1	$34,480.00	$0.00	$53,565.00	$0.00	$137,917.00	$0.00	$137,917.00	$0.00	$137,917.00	$0.00
Technicians	FTE: 6 / 8 / 9 / 10 / 10	$361,800.00	$0.00	$741,600.00	$0.00	$783,848.00	$0.00	$983,454.30	$0.00	$1,012,957.90	$0.00
Rents	satellite in MRC (735 sqft)	$11,386.16	$0.00	$17,673.75	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
	satellite in BI (771 sqft)	$11,885.05	$0.00	$18,786.25	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
	satellite in MIP (20,000 sqft)	$0.00	$0.00	$145,200.00	$0.00	$435,600.00	$0.00	$435,000.00	$0.00	$435,000.00	$0.00
consumables		$80,400.00	$40,000.00	$267,000.00	$181,137.15	$580,000.00	$344,049.33	$800,000.00	$199,938.08	$800,000.00	$104,348.52
animals		$33,500.00	$30,000.00	$50,000.00	$30,000.00	$50,000.00	$20,000.00	$50,000.00	$26,000.00	$50,000.00	$20,000.00
travel costs		$53,380.00	$53,800.00	$50,000.00	$60,800.00	$50,000.00	$60,800.00	$50,000.00	$45,600.00	$50,000.00	$45,600.00
On-site lodging	for Fraunhofer staff working at BEAM	$0.00	$27,360.00	$0.00	$27,360.00	$0.00	$27,360.00	$0.00	$27,360.00	$0.00	$27,360.00
other costs for Fraunhofer teams on site	e.g. telecommunication, WiFi, car rental	$0.00	$30,400.00	$0.00	$30,400.00	$0.00	$19,200.00	$0.00	$15,200.00	$0.00	$15,200.00
Other costs	McM industry liason office	$10,000.00	$0.00	$15,000.00	$0.00	$15,000.00	$0.00	$15,000.00	$0.00	$15,000.00	$0.00
	user fees	$48,240.00	$0.00	$160,000.00	$0.00	$336,000.00	$0.00	$480,000.00	$0.00	$480,000.00	$0.00
	conference fees	$15,000.00	$5,000.00	$20,000.00	$10,000.00	$15,000.00	$5,000.00	$20,000.00	$5,000.00	$20,000.00	$5,000.00
	publication fees	$2,000.00	$2,000.00	$5,000.00	$2,500.00	$10,000.00	$5,000.00	$10,000.00	$5,000.00	$10,000.00	$5,000.00
	patent fees and costs	$0.00	$0.00	$1,000.00	$1,000.00	$10,000.00	$10,000.00	$20,000.00	$20,000.00	$40,000.00	$20,000.00
Fraunhofer scientists @ IZI mirror group	FTE: 2 / 2 / 3 / 3 / 3 (TvöD 13)	$0.00	$359,251.52	$0.00	$363,155.40	$0.00	$366,593.92	$0.00	$561,205.32	$0.00	$561,205.32
Fraunhofer technicians @ IZI mirror group	FTE: 1 / 2 / 3 / 4 / 5 (TvöD 8)	$0.00	$113,635.84	$0.00	$230,115.84	$0.00	$350,426.88	$0.00	$474,021.12	$0.00	$592,626.40
	Sum Costs at McM/Fraunhofer	$819,415.28	$1,070,870.36	$1,821,278.00	$1,320,000.00	$3,261,723.00	$1,502,000.00	$4,210,329.30	$1,644,000.00	$4,259,332.90	$1,568,000.00
FPC Operating Costs	FPC total/yr	$1,890,284.64		$3,241,270.00		$4,769,723.00		$5,854,329.30		$5,827,332.90	

FPC Operating Funding	comments	McM	Fraunhofer	McM	Fraunhofer	McM	Fraunhofer	McM	Fraunhofer	McM	Fraunhofer
Industry funding		$250,000.00	$0.00	$300,000.00	$200,000.00	$600,000.00	$400,000.00	$1,200,000.00	$800,000.00	$1,200,000.00	$800,000.00
	Industry funding FPC total/yr	$250,000.00		$500,000.00		$1,000,000.00		$2,000,000.00		$2,000,000.00	
Public project funding		$640,000.00	$160,000.00	$1,440,000.00	$360,000.00	$2,000,000.00	$500,000.00	$2,160,000.00	$540,000.00	$2,160,000.00	$540,000.00
	Public project funding FPC total/yr	$800,000.00		$1,800,000.00		$2,500,000.00		$2,700,000.00		$2,700,000.00	
McM contribution/yr		$0.00		$195,195.07		$701,961.21		$889,592.80		$912,508.32	
Fraunhofer IZI contribution/yr			$508,000.00		$380,000.00		$280,000.00		$178,000.00		$178,000.00
Fraunhofer Central contribution/yr			$252,000.00		$380,000.00		$323,000.00		$126,000.00		$92,000.00
Fraunhofer in-kind			$0.00		$0.00		$0.00		$0.00		$0.00
	Contributions total/yr	$760,000.00		$956,195.07		$1,309,961.21		$1,193,592.80		$1,140,508.32	
FPC Operating Funding	Total funding FPC/yr	$1,810,000.00		$3,256,195.07		$4,809,961.21		$5,893,592.80		$5,840,508.32	

							total balance
FPC Balance		-$80,284.64	$14,922.07	$29,238.21	$39,263.50	$12,675.39	$6,564

Next to this, Fraunhofer will provide material in kind-support (see chapter 8.3.2) and personnel in kind support (visiting scientists and undergraduate students) to BEAM, at least summing up to $220,000 annually (expected average volume: $500,000 annually).

Fraunhofer is expected to benefit from industrial funding by 40% in form of subprojects. For public funding, an average share of 20% is used for this calculation. This is a conservative estimation. If possible, Fraunhofer will also contribute to publically funded projects with 40%.

11 Outreach and perspectives

After five years of successful work the FPC is expected to comprise at least 15 projects performed by about 70 managers, scientists, technicians, and guests. Some guest researchers or representatives from partner companies are expected to be continuously present at FPC in Hamilton.

Furthermore, FPC will be recognized internationally not only for its scientific excellence, but in particular for its well-organized product-oriented R&D projects in the field of bioengineering, advanced manufacturing and cell therapy development which are of utmost relevance for sustained commercialization to its industrial partners. This is reflected by the FPC funding structure, being composed of 60% coming from the private and industry sectors and 40% coming from public sources.

FPC will have been established as one of McM's most vital, active and successful close-to-market R&D institutions, closely collaborating with established McM life science institutes. Continuously generated scientific output, generated IP, acquired grant volume and realized license fees contribute to McM's excellent standing in both the scientific and the industrial environment. Fraunhofer IZI will benefit from IP and its commercialization. It will also conduct subprojects being handed to IZI from FPC to ensure an additional partner benefit. The volume of these funds is expected to be 40% for all projects (see Framework Agreement, **section IV.4** for details). These funds will contribute to additional technology and product developments at IZI for FPC.

Highly promising results with excellent market perspectives secured by own intellectual property rights and/or recommendations by potential investors even during the first five year period may lead to foundation of spin-off companies. FPC initiators may hold shares in some of these companies. These companies are expected to take over close-to-market inventions by purchasing IP rights or taking licenses from FPC for commercialization.

As outlined in **chapter 9.5.2**, the initiators McM and the Fraunhofer-Gesellschaft will decide on FPC's future perspectives after the 4.5-year evaluation turn. The FPC initiators expect the centre to be successful, so a continuation of FPC in the same frame i.e. as Fraunhofer Project Centre is the minimum aim. In case of performance indicators exceeding the figures given by this business plan, FPC could be upgraded to a Fraunhofer Centre under a new, to-be-founded legal entity of Fraunhofer in Canada, Fraunhofer Board of Director's agreement and additional factors such as basic funding from public (Canadian) sources permitting.

In case of failure or disagreement of the partners the FPC initiative will be terminated.

Highly promising results with excellent market perspectives secured by own intellectual property rights and/or recommendations by potential investors even during the first five year period may lead to foundation of additional spin-off companies from FPC.

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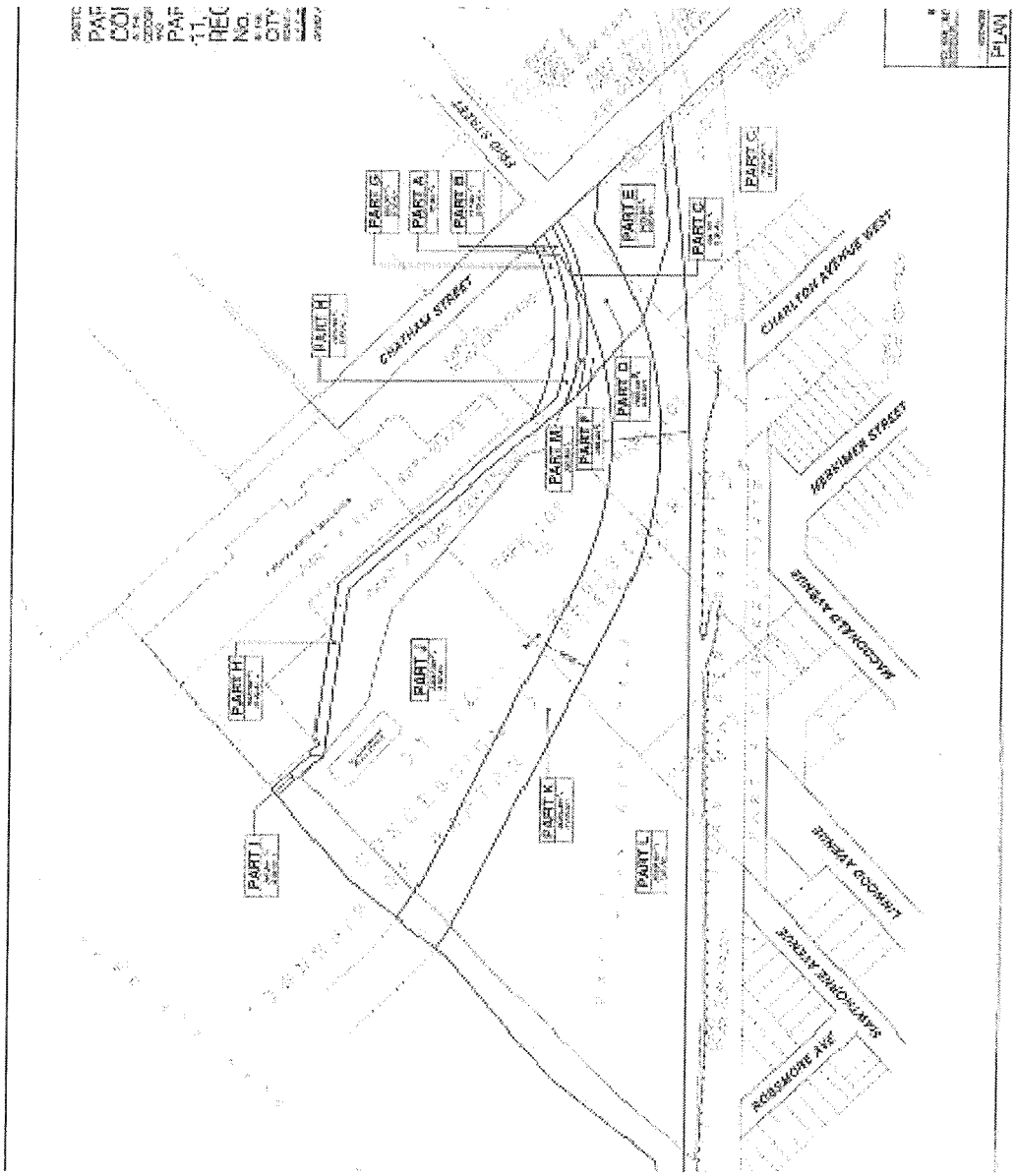
Canadian Asset Map for Stem Cell and Regenerative Medicine: Overview of Stem Cell and Regenerative Medicine Research in Canada (http://www.ic.gc.ca/eic/site/lsg-pdsv.nsf/eng/hn01746.html

Schedule "B"- Legal Description of Lands

That, subject to the approval of Recommendations (a) and (b) of Report PED14091(a), that the subject site described as Part Lot 20, Concession 3, Barton; Part Park Lots 11, 12, 15, and 16, A., MacNab Survey (aka OM1434); designated as Parts 1, 2, 7, 11, 13 and 15 on Reference Plan 62R-17420; subject to Rights-of-Ways and easements over the lands designated as Part 7 on Reference Plan 62R-17420, as described in Instrument No. CD331623 and CD 342223; subject to an easement over the lands designated as Part 2 on Reference Plan 62R-17420, as described in Instrument No. NS290560; City of Hamilton; and Part Park Lots 11 and 14, A. MacNab Survey, being Parts 1, 2, 3 and 4, Plan 62R-10973 (aka OM1434); together with an Easement as in NS290560, now partially release as to Part 1 on Plan 62R-18835, as in WE715100; subject to an Easement as in HL262531; save and except Parts A, B, C, D and K on Plan No. RC-H-676A Surveys, City of Hamilton, comprising a lot area of 14.825 acres, be declared surplus to the requirements of the City of Hamilton, in accordance with the "Sale of Land Policy By-law", being By-law No. 14-204;

Note: Plan No. RC-H-676A is the second page of this schedule and will be converted to a reference plan that will be registered on title prior to the transfer of the Lands to the University.



Schedule "C"- Legal Description of Property

LT 8, Registrar's Compiled Plan 1479, Parts 1, 2, 3 and 4 on 62R3576; save and except Parts 1, 2, 3, 4, 5 and 6 on 62R19193; S/T CD55731, except the T/W therein; City of Hamilton

Schedule "D" – Budget

High Level Overview of 5 year Budget

Use of Funds	Amount	Source
Stationary Site Preparation for FMPC at MIP	$4M	McMaster – value of land and building (40,000 sq ft @ $100)
Architect and building permits	$1.6M	MRI
Construction / Renovations for 20,000 sq ft of FMPC office and lab space (Phase 1)	$6M	Fed Dev, City of Hamilton

Large Equipment Costs for FMPC manufacturing capabilities	$5M	Fed Dev
Operational Expenses for FMPC	$18.9M	Industry contracts, Fraunhofer-IZI, Government grants, MRI, Fed Dev

Annual breakdown of Budget (estimated)

Year 1 – May 2014 to April 2015

Use of Funds	Amount	Source
Stationary Site Preparation for FMPC at MIP	$4M	McMaster – value of land and building (40,000 sq ft @ $100)
Architect and building permits	$1.6M	MRI
Construction / Renovations to begin for 20,000 sq ft of FMPC office and lab space	$2M	City of Hamilton
Operational Expenses for FMPC at McMaster Campus (transition phase)	$800K + $1.07M	Industry contracts, MRI Fraunhofer IZI

Year 2 - May 2015 to April 2016

Use of Funds	Amount	Source
Construction / Renovations completed for 20,000 sq ft of FMPC office and lab space	$4M	City of Hamilton, Fed Dev
Large Equipment Purchases for FMPC Manufacturing	$3M	Fed Dev
Operational Expenses for FMPC at McMaster campus until Dec. 2015 and MIP thereafter (stationary phase to start January 2016)	$1.89	Industry contracts, MRI, Fed Dev, government research grants

	$1.12M	Fraunhofer IZI

Year 3 - May 2016 to April 2017

Use of Funds	Amount	Source
Large Equipment Purchases for FMPC Manufacturing	$2M	Fed Dev
Operational Expenses for FMPC at MIP	$3.3 $806K	Industry contracts, MRI, Fed Dev, government research grants Fraunhofer IZI

Year 4 - May 2017 to April 2018

Use of Funds	Amount	Source
Operational Expenses for FMPC at MIP	$4.22M $754K	Industry contracts, government research grants, commercialization revenues, MRI, Fed Dev Fraunhofer IZI

Year 5 - May 2018 to April 2019

Use of Funds	Amount	Source
Operational Expenses for FMPC at MIP	$4.25M +	Industry contracts, government research grants, commercialization revenues, MRI, Fed Dev

	$655K	Fraunhofer IZI

Schedule "E" – Timelines

Timelines for FMPC development including responsibilities

Milestone	Timepoint	Comment	Responsibility
Future management teams, University / Fraunhofer leaders work on the FPC concept and the business plan	01 – 04/2014	none	Management team
Business plan finalized and submitted	06/2014	none	Management team
Decision by Fraunhofer Board of Directors	08/2014	business plan approved, framework agreement negotiated and agreed upon in most crucial issues	Board of Directors
Framework agreement negotiated, closed and signed	08/2014	to be negotiated in parallel to business plan evaluation process by Fraunhofer Board of Directors	University and Fraunhofer legal representatives
Management team is inaugurated	08/2014	after FhG Board decision	University / Fraunhofer
FPC starts officially, first (internal) projects implemented	09/2014	solemn joint opening ceremony, Framework agreement is officially signed	Management team
First ORF grants completed and submitted	07/2014	under preparation since 01/2014	Management team
Transitional phase FPC facility operational, first visiting scientists arrive to FPC	10/2014	none	Management team
Project acquisition for FPC starts	10/2014	none	Management team
Construction schedule for FPC stationary phase* finalized with University officials (*Stationary phase refers to FPC at its permanent space at MIP)	01/2015	none	Management team and responsibleUniversity officers
First external project granted to FPC	02/2015	none	Management team
Hiring of transitional phase	03/2015	some reserve time	Management team

personnel completed		included as highly qualified staff may not be available on demand	
Construction for FPC stationary phase* starts	03/2015	none	Responsible University officers
External project volume attracted to FPC exceeds $1.5 M CAD	03/2016	none	Management team
FPC review (1.5-year term)	03/2016	see suggested criteria	Management team
Submission of evaluation reports	04/2016	Filing of the evaluation reports	Management team
Review of evaluation reports and decision	06/2016	Referee team meeting 15th June	Referee team
Completion of FPC stationary phase	03/2016	none	Construction teams/ University officers
External project volume attracted to FPC exceeds $2.0 M CAD	03/2016	none	Management team
Stationary phase completely operational	04/2016	all equipment delivered	Management team
First industry partner subsidiary on site at FPC	06/2016	none	Management team
Hiring for FPC stationary phase completed	10/2016	none	Management team
External project volume attracted to FPC exceeds $6.0 M CAD	03/2018	none	Management team
External project volume attracted to FPC exceeds $8.0 M CAD	03/2019	none	Management team
FPC review (4.5-year term)	03/2019	see suggested criteria	Management team
Submission of evaluation reports	04/2019	Filing of the evaluation reports	Management team
Review of evaluation reports and decision	06/2019	Referee team meeting 15th June	Referee team
Application for FPC continuation filed to Fraunhofer Board of	07/2019	in case 4.5-year evaluation criteria were	Management team

Directors and University		met	
Decision on FPC continuation at Fraunhofer Board of Directors and McMaster University	09/2019	none	Fraunhofer Board of Directors / McM representatives

**Stationary Phase refers to when FMPC is re-located to its permanent space at MIP

Schedule "F" – Reports

Name of Report	Due Date	Report Content

1. Use of Funds Report pursuant to section 4.3.2 of this Agreement	Within 30 days after the advance of Grant 2.	As described in section 4.3.2 of this Agreement.
2. FMPC Semi-Annual Reports as described in section 7.1.2 of the Business Plan attached as Schedule "A" to this Agreement	No later than June 15th and November 30th of each year of the Term after the Commencement Date	As described in section 7.1.2 of the Business Plan attached as Schedule "A" to this Agreement
3. University Schedule of Funding and Expenditures FMPC pursuant to section 6.2 of this Agreement	October 31st of each year of the Term	As described in section 6.2 of this Agreement.
4. Final Schedule of Funding and Expenditures FMPC pursuant to section 6.2	Within 30 days of the expiration of the Term	As described in section 6.2 of this Agreement.
5. Unspecified Reports pursuant to section 7.1(b) of this Agreement	On a date or dates to be specified by the City.	As specified by the City.
6. City's Annual Report as required pursuant to section 10.1 of this Agreement	June 15th for each of the five years from the Commencement Date	As described in section 10.1 of this Agreement

Final as approved (see last page)

McMASTER UNIVERSITY
HAMILTON HEALTH SCIENCES
ST. JOSEPH'S HEALTHCARE HAMILTON

JOINT INTELLECTUAL PROPERTY POLICY

1 Introduction and Objectives

1.1 The purpose of McMaster University (hereinafter the "University"), Hamilton Health Sciences ("HHS") and St. Joseph's Healthcare Hamilton ("SJHH") includes the discovery, communication, and preservation of knowledge. The vision of the University, HHS and SJHH includes the achievement of international distinction for creativity, innovation and excellence.

1.2 Discoveries are an objective of the University, HHS and SJHH (collectively the "Institutions"). As a part of their obligation to society in general, the Institutions and their members have a responsibility to communicate these discoveries to the public. Some of these discoveries may have commercial value which should be exploited to the mutual advantage of those concerned. If the use of these discoveries can be limited or controlled by physical or legal means, the discoveries may also be referred to as "intellectual property."

1.3 The objectives of this policy are to:

(a) encourage any member of the Institutions who may have created or discovered intellectual property to disseminate that property to the public in a manner that benefits both the member and the Institutions;

(b) recognize and uphold the principles of academic and research integrity in the possible commercialization of intellectual property;

(c) develop a body of knowledge and expertise within the Institutions in order to permit the continued successful commercialization of intellectual property in the future;

(d) outline clearly the ownership rights in any newly created or discovered intellectual property as between the Institutions and their members and the obligation for related costs and the division of related revenues;

(e) provide for the rights and obligations of the Institutions and their members in protecting and exploiting any newly created or discovered intellectual property;

(f) provide exclusions for certain types of intellectual property from this policy; and

(g) provide for the rights and obligations of the Institutions among themselves for the responsibilities and benefits arising under this policy.

1.4 It is possible that, at times, the academic and research missions of the Institutions may conflict with the potential commercialization of intellectual property. As the academic and research missions of the Institutions should take priority, the following principles shall take precedence over any other aspect of this policy where applicable:

(a) Academic Researchers, as defined in section 2.1, have the right initially to determine whether or not any new creation or discovery for which they are responsible should be commercialized. Prior to making such a decision, the Institutions may be asked to review any such creation or discovery and provide advice on the possible commercial value thereof. In spite of such a review, the Academic Researcher shall be solely responsible for the decision to proceed with commercialization;

(b) Members of the Institutions who are involved in the commercialization of any creation or discovery may be asked to withhold publication of any material or not to make any presentation thereof only for a reasonable period of time not exceeding six (6) months from the time full disclosure is made. This period of time shall be used to assess the intellectual property and to allow for any applicable legal protection to be put into place;

(c) No member of the Institutions shall be required to engage in any work or research which prohibits the results of the work or research from publication or disclosure to the public unless:

(i) that person is engaged in a position where it is contemplated that they would not normally be expected to publish the result of their work or research; or

(ii) that person provides their informed consent to engage in such work or research, and, in the case of any Student, their involvement in the work or research does not conflict or jeopardize the timely completion of any academic requirements and that the Institutional Student Affairs Office, as that term is defined in section 2.4 below, has agreed to such participation.

2 Definitions

In this policy, the following terms, when capitalized, shall have the following meanings:

2.1 "Academic Researcher" means someone who is a Member of the Institutions and whose appointment contemplates that they will conduct research and be responsible for the publication or other dissemination of the results of that research or be responsible for teaching of Students. For greater certainty and without limitation, an Academic Researcher shall include:

(a) a member of the University Teaching Staff; and

(b) someone who holds an appointment to the medical staff of SJHH or HHS;

and shall not include:

(c) a research technician;

(d) a research nurse; or

(e) any other staff member who works under the direct supervision of an Academic Researcher.

The determination of who is an Academic Researcher shall be the responsibility of the IP Board;

2.2 "Disclosure Form" means the form established under section 7 hereof;

2.3 "HHS" means Hamilton Health Sciences Corporation incorporated under the laws of the Province of Ontario.

2.4 "Institutional Student Affairs Office" means the office of the institution (which may include institutions such as hospitals, universities and community colleges other than SJHH, HHS and the University) that is responsible for the academic progress of a student. For a University Student that is enrolled in a graduate program it is the School of Graduate Studies; for a University Student that is enrolled in an undergraduate program it is the Dean's office of the relevant Faculty. The determination of which is the correct office shall be the responsibility of the IP Board;

2.5 The "IP Board" means the Joint Institutional Intellectual Property Board created herein and comprises the membership described in section 3.5;

2.6 "IP Creator" has the meaning defined in section 5.1 hereof;

2.7 "Intellectual Property" means databases, audio-visual material, electronic circuitry, biotechnology and genetic engineering products, computer software recorded in any format, inventions, discoveries and all other products of research (which inventions, discoveries or other products are capable of protection pursuant to any law of Canada or any other country or which may be otherwise licens-

able) where any of the foregoing are created, whether by discovery, invention or otherwise by an IP Creator as hereinafter defined;

2.8 "Member of an Institution" or "Member of the Institutions" or any similar phrase means anyone who:

(a) holds any appointment as a member of the medical staff of any of the Institutions;

(b) is a member of the University Teaching Staff'

(c) is an employee of any type of any of the Institutions;

(d) holds any other type of office or privileges at any of the Institutions; or

(e) is a Student at any of the Institutions.

2.9 "ORCIP" means the Office of Research Contracts & Intellectual Property of the University;

2.10 "SJHH" means St. Joseph's Healthcare Hamilton, a division of the St. Joseph's Health System;

2.11 "Student" includes:

(a) a University Student;

(b) a person following a program at any of the Institutions as a Post-Doctoral Fellow, Clinical Fellow, Medical Intern or Medical Resident; and

(c) anyone else who is engaged in a course of study at any of the Institutions or at any other institution (which may include institutions such as hospitals, universities and community colleges other than the Institutions).

The determination of who is a Student shall be the responsibility of the IP Board;

2.12 the "University" means McMaster University created under the *McMaster University Act, 1976;*

2.13 "University Student" has the same meaning as the term "student" is defined in the *McMaster University Act, 1976*;

2.14 "University Teaching Staff" has the same meaning as the term "teaching staff" is defined in the *McMaster University Act, 1976*;

3 Responsibility for this Policy

3.1 ORCIP is responsible for providing the administrative needs of this policy.

3.2 The Executive Director of the ORCIP is responsible for the administration of this policy and shall be responsible to the Vice-President (Research and International Affairs) of the University

3.3 The Vice-President (Research and International Affairs) of the University shall consult as necessary with the Vice-President Research and Corporate Development of HHS and the Vice-President Research of SJHH on the operations of the ORCIP (the three Vice-Presidents being the "Institutional Vice-Presidents").

3.4 The Intellectual Property Board of the University existing at January 1, 2005, is continued as the Joint Institutional Intellectual Property Board.

3.5 The Joint Institutional Intellectual Property Board shall consist of the following members:

(a) Vice-President (Research & International Affairs) of the University, who shall act as Chair of the Board;

(b) Vice-President, Research and Corporate Development of HHS, who shall act as a vice-Chair of the Board;

(c) Vice-President, Research of SJHH, who shall act as a vice-Chair of the Board;

(d) The Executive Director of the ORCIP, who shall act as Secretary of the IP Board;

(e) Five (5) members of the University Teaching Staff appointed by the President of the University, after consultation with the Vice-President (Research & International Affairs) and the President of the McMaster University Faculty Association;

(f) Three (3) other persons who have experience in the commercialization of intellectual property appointed by the Board of Governors of the University on the recommendation of the President of the University;

(g) Two Academic Researchers of HHS appointed by the President of HHS, after consultation with the Vice-President, Research and Corporate Development of HHS;

(h) One (1) other person who has experience in the commercialization of intellectual property appointed by the Board of Directors of HHS on the recommendation of the President of HHS;

(i) Two Academic Researchers of SJHH appointed by the President of SJHH, after consultation with the Vice-President, Research of SJHH;

(j) One (1) other person who has experience in the commercialization of intellectual property appointed by the Board of Trustees of SJHH on the recommendation of the President of SJHH.

Terms for those described in paragraphs (e) through (j) above shall be for a term of up to three (3) years which may be extended for no more than two (2) additional terms.

3.6 The IP Board shall from time to time establish its own rules of procedure which shall be consistent with practices within the Institutions. Such rules shall also provide that when the IP Board is acting in a quasi-judicial fashion in making decisions that rules of natural justice shall be applied.

3.7 Quorum of the IP Board shall be a simple majority thereof provided that there shall be at least two members present from an Institution when dealing with any matters arising from that Institution.

3.8 The duties of the IP Board shall include:

(a) the specific decisions referred to in sections 2.1, 2.4, 2.11, 3.6, 4.3(d), 4.4, 6.4, 6.6, 7.1, 10.2, 10.3, 11.2, 12, 13.3, 14.3, 14.4, 14.8, 15.2 and 16 hereof;

(b) preparing an annual report to the Senate and Board of Governors of the University, the Board of Directors of HHS and the Board of Trustees of SJHH on intellectual property and its commercialization;

(c) the recommendation to the Senate and the Board of Governors of the University, the Board of Directors of HHS and the Board of Trustees of SJHH of any revisions required to this or any other Institutional Policy relating to intellectual property;

(d) the resolution of issues of disputed discovery among two or more IP Creators of the same intellectual property, the entitlement to any portion of Net Revenues of any IP Creator or the division of Net Revenues as between IP Creators; and

(e) the resolution of any other issues relating to the commercialization of intellectual property at the Institutions including, without limitation, the decision whether or not to proceed with commercialization in the case of joint IP Creators where there is no unanimous agreement among them as to commercialization.

3.9 The IP Board has exclusive jurisdiction over the application, interpretation and administration of this policy. Any claim made by any IP Creator or anyone making any claim hereunder shall be submitted to the IP Board for final determination.

3.10 Every order, decision or proceeding of the IP Board is final and shall not be questioned, reviewed, prohibited or restrained by any court or be made the subject of any proceedings in or any process of any court, whether by way of injunction or certiorari or otherwise on any ground, including the ground that the order, decision or proceeding is beyond the jurisdiction of the IP Board.

4 Intellectual Property Covered by this Policy

4.1 Intellectual Property has the meaning defined in section 2.7 hereof.

4.2 In the case of members of the Institutions who are not Academic Researchers, Intellectual Property shall include anything created or discovered by them when the terms of their employment require them to engage in the activity that resulted in the creation or discovery;

4.3 Intellectual Property shall not include:

(a) copyright in traditional academic materials such as, without limitation, lecture notes, laboratory manuals, articles, books, artifacts, works of visual art, maps, charts, plans, photographs, engravings, sculptures and music, no matter in which format any of the foregoing materials may have been recorded or embodied including, without limitation, a computer readable format, where any of the foregoing material has been created by someone who is an Academic Researcher unless they have otherwise agreed to treat any such material as Intellectual Property hereunder;

(b) computer software that is either ancillary to or the functional equivalent of any of the items described in paragraph (a) hereof where such material has been created by someone who is an Academic Researcher;

(c) anything created or discovered by a member of the Institutions in the course of demonstrably private research outside of their normal Institutional duties or in the course of activities as a consultant to outside persons when such consulting activities otherwise comply with applicable Institutional policies on such activities and have been properly reported as required by those policies;

(d) provided that there has not been a significant use of Institutional resources (the level of which shall be determined by the IP Board) and provided that the work otherwise complies with applicable Institutional policies, anything independently created or discovered by a Student as part of the academic requirements of a program or course of study; or

(e) any material which is in the public domain.

4.4 Any member of the Institutions can seek a binding opinion from the IP Board as to whether or not any particular matter is or is not Intellectual Property within the scope of this policy.

5 Persons Covered by this Policy

5.1 In this policy, the term "IP Creator" means an individual who:

(a) creates or discovers any Intellectual Property; and

(b) is any one of:

(i) a member of any of the Institutions; or
(ii) a person who is permitted to use any facilities of any of the Institutions in a manner which is normally not available to a member of the general public except on special request.

5.2 Acceptance of the terms and conditions of this policy shall be a condition of appointment, employment, enrolment, or use as the case may be, of:

(a) every member of any of the Institutions; and
(b) every person who is permitted to use any facilities of any of the Institutions in a manner which is normally not available to a member of the general public except on special request.

5.3 This policy shall come into force on January 1, 2005. All matters related to Intellectual Property at any of the Institutions shall be governed by this policy after this date.

6 Decision to Commercialize

6.1 An IP Creator who is an Academic Researcher may make the decision to commercialize any newly created or discovered Intellectual Property. The decision and the disclosure of the creation or discovery must be made and communicated to the Institutions at least six (6) months prior to any publication or presentation that would have the effect of putting the new Intellectual Property in the public domain.

6.2 In the event that a decision to commercialize any newly created or discovered Intellectual Property has the effect of requiring any Student to be delayed in the presentation of any material required for the successful completion of the Student's academic requirements, the delay cannot be more than six (6) months from the time that the Student first advises the Institutional Student Affairs Office and the ORCIP of the Student's ability to make such a presentation.

6.3 A decision to commercialize any Intellectual Property shall bind the IP Creator to the procedure established by this policy.

6.4 In the event that any newly created or discovered Intellectual Property is the result of the joint effort among more than one IP Creator, the decision to commercialize may proceed with the unanimous consent of the joint IP Creators failing which the matter will be referred to the IP Board for a decision.

6.5 In the case of any newly created or discovered Intellectual Property created by someone who is not an Academic Researcher, the decision to commercialize shall be made by that person's supervising Academic Researcher or the Vice-President of the relevant administrative unit of the applicable Institution.

6.6 In the case of any newly created or discovered Intellectual Property created by a Student, the decision to commercialize may proceed with the unanimous consent of:

(a) the Student;
(b) the Student's academic supervisor;
(c) any other collaborators; and
(d) the senior officer of the applicable Institutional Student Affairs Office.

In the event that there is no unanimous agreement the matter shall be referred to the IP Board for a decision.

6.7 In the event that a decision is made not to commercialize any newly created or discovered Intellectual Property, such Intellectual Property shall be, for the purposes of this policy, considered to have been dedicated to the public domain from the date of the first publication describing the Intellectual Property.

7 Disclosure

7.1 A disclosure to the Institutions of the creation or discovery of any new Intellectual Property shall be made in the form established by the IP Board from time-to-time (hereinafter the "Disclosure Form.") The ORCIP shall provide reasonable assistance to the IP Creator in the completion of the Disclosure Form.

7.2 A copy of the Disclosure Form shall be sent to the appropriate Departmental Chair.

7.3 In some cases, an IP Creator may wish to provide limited disclosure of the creation or discovery of any new Intellectual Property to third parties. Such disclosure shall be permitted only if the IP Creator has arranged for the third parties receiving such information to have signed a non-disclosure agreement in form and substance satisfactory to the Institutions.

7.4 In some cases, a member of the Institutions may wish to provide material or products (such as, without limitation, biological or genetic samples) to third parties. Such material or products may be transferred only if the member of the Institutions has arranged for the third parties receiving such material or products to have signed a material transfer agreement in form and substance satisfactory to the Institutions.

8 Receiving Disclosures and Materials

8.1 In some cases, members of the Institutions may wish to receive disclosure from third parties of the creation or discovery of intellectual property of those third parties. The receipt of such disclosure shall be permitted if the IP Creator has entered into appropriate arrangements in form and substance satisfactory to the Institutions with the third parties providing such disclosure.

8.2 In some cases, members of the Institutions may wish to receive material or products (such as, without limitation, biological or genetic samples) from third parties. Such material or products may be received only if the member has entered into appropriate arrangements in form and substance satisfactory to the Institutions with the third parties providing such materials or products.

9 Initial Ownership of Intellectual Property

9.1 Subject to section 15.4 hereof, the University shall be the nominal owner of all newly created or discovered Intellectual Property arising at any of the Institutions.

9.2 An IP Creator shall only deal with newly created or discovered Intellectual Property in accordance with this policy.

9.3 Notwithstanding sections 9.1 and 9.2 hereof, certain agreements (such as grants, sponsorships, research and affiliation agreements) have been or will be entered into by the Institutions with third parties. Such agreements may contain provisions whereby Intellectual Property is transferred, assigned, licensed or otherwise disposed of to such third parties. The provisions of such agreements shall supersede this policy:

(a) when the agreement involves the work of a Student, when the senior officer of the applicable Institutional Student Affairs Office has approved that the agreement shall so supersede; and

(b) when the applicable Institutional Vice President, and any member who is an Academic researcher who may be affected by such agreement have approved that the agreement shall so supersede;

failing which this policy shall continue to apply in precedence to such agreement.

10 Retention of Ownership Right

10.1 After a Disclosure Form has been received by the ORCIP, a review will be conducted which will include an assessment of the potential commercial value of the Intellectual Property.

10.2 With respect to any Intellectual Property, the IP Board may decide that:

(a) the Institutions are interested in proceeding with the protection and commercialization of the intellectual Property; or

(b) the Institutions have no further interest in the Intellectual Property.

10.3 In the case where the IP Board has decided that the Institutions have no further interest in the Intellectual Property, the Intellectual Property may:

(a) at the request of the applicable Institution other than the University, be transferred to that Institution on such terms and conditions as the IP Board may prescribe; or

(b) failing such an Institutional request, and at the request of the original IP Creator, and subject to section 12, be transferred to the IP Creator on such terms and conditions as the IP Board may prescribe.

11 Transfer of Institutionally-Owned Intellectual Property

11.1 An IP Creator who is an Academic researcher may request that ownership of Intellectual Property be transferred to the IP Creator. Such a request may only be made with respect to Intellectual Property for which a Disclosure Form has been filed. A decision by the IP Board on the IP Creator's request shall be made within six (6) months provided that the Institutions and IP Creator may agree in writing to further extensions of this time as may be required.

11.2 The IP Board shall not unreasonably withhold approval of the IP Creator's request. The IP Board's approval shall be subject to such reasonable terms and conditions that the IP Board may establish at the time of such approval and subject to section 12. Such terms and conditions shall take into account the provisions of section 14 providing for the sharing of revenues.

11.3 No resources of the Institutions shall be available to an IP Creator to whom Intellectual Property has been transferred except by means of an appropriate research contract. For greater certainty and without limitation, the IP Creator shall be solely responsible for any accounting or reporting requirements and the costs related to any professional advice required relating to Intellectual Property so assigned.

12 Assignments from Institutions

In the event that ownership of any Intellectual Property is being assigned away from the Institutions, the IP Board shall normally include the following terms and conditions in any such assignment:

(a) A royalty free non-exclusive perpetual licence for non-commercial academic and research purposes for the Intellectual Property in favour of the Institutions and all of the members of the Institutions while working at the Institutions;

(b) The right to reasonably consent to any further assignments or transfers of the Intellectual Property; and

(c) A Provision acknowledging that no resources of the Institutions shall be available to further develop the Intellectual Property without an appropriate research agreement.

13 Commercialization of Intellectual Property

13.1 The IP Creator shall be consulted in the commercialization by the Institutions of Intellectual Property. Such consultation will include exploring the opportunities for further research to be performed by the IP Creator or others at the Institutions, the potential revenues which may arise and the payment of costs related to patent applications and other aspects of commercializing the Intellectual Property.

13.2 The IP Creator shall have no responsibility for the payment of any costs relating to the commercialization by the Institutions of Intellectual Property.

13.3 The actual method of commercializing Intellectual Property shall be the determination of the IP Board.

13.4 In the event that the IP Board determines that the Institutions no longer wish to continue to commercialize any Intellectual Property, the Institutions may discontinue such efforts provided that there are no outstanding contractual commitments relating thereto, and further provided that sections 10.3 and 12 are complied with.

13.5 ORCIP will report periodically to the IP Creator on the commercialization of Intellectual Property created by the IP Creator and the revenues arising therefrom.

14 Revenue Sharing with IP Creators

14.1 In this section, the term Gross Revenues (when used in its capitalized form) shall mean all revenue or other consideration generated by the commercialization of Intellectual Property.

14.2 In this section, the term Net Revenues (when used in its capitalized form) shall mean Gross Revenues less:

(a) all out-of-pocket direct expenses of the person pursuing such commercialization including any patent application fees or fees reasonably paid to third parties for any relevant purpose; and

(b) all deductions normally made according to generally accepted accounting practices in Canada including an appropriate allocation of any indirect costs or other direct costs of any of the Institutions relating to the generation of the Intellectual Property.

The actual determination of the components of Net Revenues in any particular case shall be the determination of the IP Board.

14.3 With respect to any Intellectual Property commercialized by the Institutions the IP Board shall decide that the Net Revenues shall be paid in the following fashion:

(a) 50% of Net Revenues shall be retained by the Institutions; and

(b) 50% of Net Revenues shall be paid to the IP Creators or reinvested in further research. The actual proportion to be paid to the IP Creators or reinvested in further research shall be decided by the IP Board based on any representations that the IP Creator wishes to make.

Provided that the IP Board may decide in the case of IP Creators that are not Academic Researchers and at the request of the Institution or Institutions involved that some other lesser portion of Net Revenues shall be paid to the IP Creators the actual percentage of which shall be the sole determination of the IP Board based on any representations that the Institution involved or the IP Creator wishes to make.

14.4 With respect to any Intellectual Property commercialized by the IP Creator, the Institutions shall normally require that they be paid twenty-five percent (25%) of the Net Revenues arising from the commercialization of the Intellectual Property. The IP Board, based on any representations that the IP Creator wishes to make, shall decide what proportion of the Net Revenues accruing to the IP Creator shall be paid to the Institutions.

The actual percentage to be used in a particular case shall be the decision of the IP Board and shall take into account the nature of the Intellectual Property and its likely method of commercialization and whether the Institutions have the potential for generating further research contracts relating to the Intellectual Property.

14.5 In the event that any return on Intellectual Property that is commercialized is in the form of an equity investment, the foregoing percentages shall be considered in determining an equitable sharing of such equity between the Institutions and the IP Creator.

14.6 Any monies to be paid to an IP Creator shall, if in excess of $10,000 per year, be reported on and paid semi-annually and otherwise reported on and paid annually.

14.7 Prior to payment of any monies to an IP Creator, the Director shall ensure that a plan for the reimbursement of costs incurred by any of the Institutions is in place.

14.8 In the event that there is more than one IP Creator for any Intellectual Property, the IP Board, after consultation with the IP Creators, shall approve the list of IP Creators and the division of any revenues among them which shall be commensurate with their relative contributions to the Intellectual Property. Any dispute relating to either the relative contributions of multiple IP Creators or their revenue entitlement shall be decided in accordance with any applicable existing procedure or, in the event that no such procedure exists, by the IP Board in accordance with rules and procedures established by the IP Board.

15 Institutional Sharing

15.1 For the purposes of this section, the following words shall have the following meanings:

(a) "Jointly-appointed Personnel" means members of the Institutions who hold appointments to more than one of the Institutions;

(b) "HHS facilities" means research or other facilities that are clearly identified as being the responsibility of HHS;

(c) "SJHH facilities" means research or other facilities that are clearly identified as being the responsibility of SJHH; and

(d) "University facilities" means research or other facilities that are clearly identified as being the responsibility of the University.

15.2 The Institutions shall share the Net Revenues arising under section 13 hereof as follows:

(a) In the case of Intellectual Property arising from work done by someone who is a member of the University and is not Jointly-appointed Personnel and that work does not involve the use of HHS facilities or SJHH facilities, the University shall receive 100% of the Institutional share;

(b) In the case of Intellectual Property arising from work done only in University facilities by someone who is Jointly-appointed Personnel, the University shall receive 50% of the Institutional share and, if the person holds only one additional appointment, the Institution to which the person holds the additional appointment shall receive 50% of the Institutional share or, if

the person holds appointments to both HHS and SJHH, HHS and SJHH shall each receive 25% of the Institutional share.

(c) In the case of Intellectual Property arising from the use of HHS facilities alone or only in combination with University facilities, the University shall receive 50% of the Institutional share and HHS shall receive 50% thereof;

(d) In the case of Intellectual Property arising from the use of SJHH facilities alone or only in combination with University facilities, the University shall receive 50% of the Institutional share and SJHH shall receive 50% thereof; and

(e) In the case of Intellectual Property arising from the use of facilities at both of HHS and SJHH, the University shall receive 50% of the Institutional share, and SJHH and HHS shall each receive 25% of the Institutional share.

15.3 All of the costs related to the operation of ORCIP shall be paid by the University and only applied against the commercialization of any Intellectual Property as provided for in Section 14 hereof.

15.4 In the case of Intellectual Property arising from the use of either SJHH facilities or HHS facilities alone by someone who is only a member of SJHH or HHS and is not Jointly-appointed Personnel, SJHH or HHS, as the case may be, may, on a case-by-case basis agree with the University as represented by ORCIP that section 9.1 shall not apply and that SJHH or HHS, as the case may be, shall be the initial nominal owner of the Intellectual Property.

15.5 If any dispute arises among the Institutions either relating to any matter in this section 15 or with respect to any other matter under this policy, the Institutions agree to work in good faith to resolve their differences amicably. The Institutions agree to the following series of steps in the event that they are not able to resolve any such dispute:

(a) Initially, the Institutional Vice-Presidents in person shall meet to attempt to resolve the issue;

(b) If the foregoing meeting fails to resolve the issue, a meeting shall be convened including the Presidents of the Institutions and the Chairs of the University Board of Governors and the Board of Trustees of SJHH and the Board of Directors of HHS all in person and without delegates to attempt to resolve the issue;

(c) If the foregoing meeting fails to resolve the issue, the matter shall be arbitrated by a panel of three arbitrators pursuant to the *Arbitrations Act* (On-

tario) each Institution choosing one of the three arbitrators. Any such arbi- tral decision will be final and not subject to any further review.

16 Quinquennial Review

This policy shall be reviewed by the IP Board prior to January 1, 2010. The IP Board shall, as part of such review, provide recommendations for the improvement of this policy.

REVISION HISTORY

Original University Policy

Approved by Senate: May 27, 1998
Approved by Board of Governors: June 11, 1998

Joint Institutional Policy

Approved by University Senate: June 9, 2004
Approved by University Board of Governors: June 10, 2004
Approved by HHS Board of Directors: June 22, 2004
Approved by SJHH Board of Trustees: June 17, 2004

END OF POLICY