FINAL RESEARCH AGREEMENT FOR A PROJECT ON HYIYIU ANTI-DIABETIC PLANT MEDICINES

AMONG

Université de Montréal, a legal person and non-profit educational institution, with an address at 2900 Édouard-Montpetit, Montréal, Québec, Canada H3T 1J4, hereby represented by its Vice-rector-Research, Mr Joseph Hubert and its Secretary general, Ms Francine Verrier duly authorized as they so declare

(hereinafter referred to as "MONTRÉAL")

Centre hospitalier de l'Université de Montréal, a constituted corporation under An Act Respecting Health Services and Social Services, R.S.Q., chapter S-4.2, a law of Quebec, Canada, having its head office at 3840 St. Urbain Street, Montréal, Québec, H2W 1T8, Canada, hereby represented by Dr. Jacques Turgeon, Director of Research and M. Serge LeBlanc, Acting Executive Director,, duly authorized as they so declare

(hereinafter referred to as "CHUM")

McGill University, a non-profit educational institution, with an address at 845Sherbrooke Street West, Montréal, Québec, Canada, H3A 2T5, hereby represented by Sandra Crocker, Assistant Vice-Principal, duly authorized as she so declares(hereinafter referred to as "MCGILL")

University of Ottawa, a non-profit educational institution, with an address at 550 Cumberland St. Rm. 246, Ottawa, Ontario, Canada K1N 6N5 hereby represented by Dr. Mona Nemer, VP Research, duly authorized as she so declares (hereinafter referred to as "OTTAWA")

(hereinafter collectively referred to as the

"Academic Institutions")

AND

Cree Board of Health and Social Services of James Bay, a public body duly constituted under An Act respecting health services and social services for Cree native persons with an address at Chisasibi, Québec J0M 1E0 hereby represented by Mabel Herodier, Executive-Director duly authorized as she so declares

(hereinafter referred to as "CBHSSJB")

AND

The Cree Nation of Mistissini, constituted as a corporation by the Cree-Naskapi (of Québec) Act, S.C. 1984, c. 18, with an address at Isaac Shecapio Sr. Administration Building, 187, Main Street, Mistissini, Quebec, G0W 1C0, hereby represented by Chief John Longchap, duly authorized as he so declares

The Whapmagoostui First Nation, constituted as a corporation by the Cree-Naskapi (of Québec) Act, S.C. 1984, c. 18, with an address at PO Box 390, Whapmagoostui, Quebec, JOM 1G0 hereby represented by Chief Losty Mamianskum, duly authorized as he so declares

(hereinafter collectively referred to as "Participating Cree First Nations")

Effective date: April 1, 2003

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FINAL RESEARCH AGREEMENT FOR A PROJECT ON ANTI-DIABETIC MEDICINES

PREAMBLE:

WHEREAS the Iiyiyiuch know that plants come from the Creator and are to be used for the benefit of the whole Iiyiyiu community. The Iiyiyiuch have been shown how to make medicines from plants and from animals and have always used these in caring for the health of the people and the Nation. Some people have been entrusted with this knowledge in order to promote the health of the people.

WHEREAS in 2000, the Cree Nation of Mistissini passed a resolution to promote the integration of traditional medicines and healing practices into health services in Iiyiyiu Aschii. The Grand Council of the Cree Forum on Health in Oujé-Bougoumou had also recommended this to the CBHSSJB. This present project is the first step taken to put these resolutions into practice.

WHEREAS this project involves the close collaboration of Iiyiyiu Healers and Elders from the Participating Cree First Nations with scientific Researchers. The Cree traditional knowledge of plants is recognized by the Researchers as a traditional scientific endeavour, built up by generations of healers, who are intimately knowledgeable of their local natural environment, using trial and observation and oral tradition to pass on a collective knowledge. The Researchers bring modern scientific knowledge of diabetes, pharmacology, ethnobotany, nutrition science, neuroscience, clinical sciences, toxicology and phytochemistry based on generations of work by modern scientists, using a written peer-reviewed publication system to pass on the collective knowledge. The general purpose is to work together to make plant medicines available to the Iiyiyiuch and possibly to other people who could benefit from them to reduce the symptoms of diabetes.

WHEREAS with this partnership, the Healers, Elders and Researchers aim:

- · To work together for the improved health of the Iiyiyiuch and the Nation;
- To identify plant medicines that might be effective against the symptoms of diabetes;
- To learn how and why the plant medicines work against diabetes;
- To discover how livijyiuch prefer to take these plant medicines (e.g. as teas, drops, tinctures etc.);
- To find ways to make these plant medicines available to the people in the region and to transmit the knowledge relating to the plant medicines to the younger generation of Crees.

WHEREAS the intent of the CBHSSJB is to encourage and facilitate pertinent research that meets the objectives of methodological rigour, ethical compliance, community participation and intellectual freedom; protects a broad definition of "traditional knowledge"; and is carried out for the long-term benefit of the families of the communities of the Iiyiyiu Nation;

WHEREAS Canada has ratified the United Nations Convention on Biological Diversity and the Parties agree with its principles; in particular, the Parties agree that prior informed consent should be obtained from knowledge holders and benefits obtained from the utilisation of knowledge should be shared with knowledge holders;

WHEREAS the purpose of this agreement is to:

- Describe the Research Project and its objectives,
- Define the relationships between the Parties involved in the Research Project and the responsibilities of each Party in order to facilitate the carrying out of the project,
- Secure the access to and define the control of the data used for the Research Project and the results of the data analysis,
- Define how the intellectual property issues regarding "traditional knowledge" will be addressed;

WHEREAS during the course of this Research Project, all efforts will be made by the Researchers and the Research Committee, described in Section 3.1, to incorporate and address the local concerns, advice and recommendations of the Participating Cree First Nations;

WHEREAS MONTRÉAL has been awarded two grants from the Canadian Institutes for Health Research ("CIHR"), the first New Emerging Team Grant for a project entitled "Rigorous scientific evaluation of selected ant-diabetic plants: Towards an alternative therapy for diabetes in the Cree of Northern Québec" from 2003-04 to 2005-06, and the second for a project entitled "Rigorous evaluation and integration of traditional medicine in aboriginal diabetes care" from 2006-07 to 2010-11 (the "Project");

WHEREAS Dr. Pierre Haddad, Department of Pharmacology, Faculty of Medicine of MONTRÉAL, is the principal investigator for this Project ("Principal Investigator");

WHEREAS other Cree First Nations may participate in this Project;

WHEREAS the Participating Cree First Nations, the CBHSSJB and the Researchers (as individuals) originally signed an Interim Research Agreement effective April 1, 2003, which remains in effect;

NOW AND THEREFORE, THE PARTIES AGREE TO THE FOLLOWING:

1. DEFINITIONS

In this Agreement:

- 1.1 "Academic Institutions" or "Academic Institution" shall refer to MONTRÉAL, CHUM, MCGILL and OTTAWA, as well as any other non-Cree academic or health institution which has agreed to become an additional party pursuant to section 2.2.1.
- 1.2 "Concerned Participating Cree First Nations" shall mean only those Participating Cree First Nations that are concerned by an action to be taken under a section of this Agreement, for example, if they have Elders and Healers who transmitted Iiyiyiu Traditional Knowledge about an Iiyiyiu Plant which is the focus of a publication or which could be commercialized.
- 1.3 "Confidential Information" shall mean all Iiyiyiu Traditional Knowledge and interviews with members of the Iiyiyiu communities, all Results, as well as any and all other knowledge, whether patentable or not, know-how, information, and/or techniques, disclosed by one Party (referred to in this capacity as the "Provider") to another (referred to in this capacity as the "Recipient") in the course of the Research Project, including, without limiting the generality of the foregoing, all research, data, specifications, plans, drawings, prototypes, models, documents, records, instructions, manuals, papers, whether written or otherwise.
- 1.4 "Cree First Nations" shall mean: the Cree Nation of Chisasibi, the Whapmagoostui First Nation, the Cree Nation of Wemindji, the Eastmain Band, the Waskaganish Band, the Cree Nation of Nemaska, the Cree First Nation of Waswanipi and the Cree Nation of Mistissini, respectively constituted as corporations by the Cree-Naskapi (of Québec) Act, S.C. 1984, c. 18, as well as the collectivities of the Crees of Oujé-Bougoumou and the Crees of Washaw Sibi.
- 1.5 "Cree First Nation" shall mean any Cree Nation listed in paragraph 1.3 hereinabove.
- 1.6 "Crees of Oujé-Bougoumou" and "Crees of Washaw Sibi" shall mean the collectivities composed of persons identified as being affiliated respectively with the community known as Oujé-Bougoumou or the community known as Washaw Sibi, and including persons enrolled or entitled to be enrolled as Cree beneficiaries under the James Bay and Northern Québec Agreement, and acting through the Oujé-Bougoumou Eenuch Association or the Washaw Sibi Iiyiyiu Association until such time as the Oujé-Bougoumou Band and the Washaw Sibi Band are constituted as a corporation under the Cree-Naskapi (of Québec) Act, and thereafter, the Oujé-Bougoumou Band and

the Washaw Sibi Band.

- 1.7 "Data" shall mean any and all information gathered during interviews with Iiyiyiuch, made within the framework of the Research Project and the Agreement, including the master list linking the Providers to Data and the Herbarium. All Data shall be treated as Confidential Information.
- 1.8 "Elder(s) and Healer(s)" shall mean the Iiyiyiu(ch) who participate in the Research Project, some of whom identify more as healers and others as elders; some regularly dispense medicinal plants as a treatment for illness whereas others have knowledge of the plants without actually treating patients.
- 1.9 "Iiyiyiu" (singular) and "Iiyiyiuch" (plural) is the name of the Cree people of northern Quebec (sometimes known as the Eastern James Bay Cree).
- 1.10 "Iiyiyiu Plant" shall mean a plant that was named by Elders and Healers to the Research Team in the context of the Research Project as set out in APPENDIX I which remains confidential, as well as traditional medicines made from this plant.
- 1.11 "Iiyiyiu Traditional Knowledge" shall mean all knowledge, beliefs and practices transmitted by the Iiyiyiuch from generation to generation, including but not limited to know-how and technical knowledge related to Iiyiyiu Plants, provided by the Iiyiyiuch to the Research Team in the context of the Research Project.
- 1.12 "Herbarium" shall mean the collection of dried liviyiuch Plants that are mounted and classified systematically in performance of this Agreement.
- 1.13 "Intellectual Property" shall mean any intellectual property recognized by law, and shall include materials, data, concepts, know-how, formulae, inventions, improvements, industrial designs, trade-marks and trademark applications, plant breeders' rights and plant breeders' rights applications, processes, patterns, machines, manufactures, compositions of matter, compilations of information, patents and patent applications, copyrights, trade secrets, technology, technical information, software, prototypes and specifications.
- 1.14 "Joint Intellectual Property" shall mean any Intellectual Property arising from the Research Project that is created, discovered or developed by at least one Academic Institution.
- 1.15 "Normal Termination Date" shall mean March 31, 2012.
- 1.16 "Participating Cree First Nations" or "Participating Cree First Nation" shall refer to and include any Cree First Nation that is a signatory to this Agreement or which has agreed to become an additional party pursuant to section 2.3.3.

- 1.17 "Party" shall mean a party to this Agreement; "Parties", used without any qualifier, shall mean all parties to this Agreement.
- 1.18 "Provider" shall mean any person or Party providing information within the framework of this Agreement.
- 1.19 "Recipient" shall mean any person or Party receiving information, data, results, compilations or documents.
- 1.20 "Researcher" shall mean one of the investigators listed in Appendix A and "Researchers" shall mean two or more or all these investigators depending on the context. "Academic Researchers" shall mean all the investigators listed in Appendix A from the Academic Institutions.
- 1.21 "Research Project" shall mean the research project more fully described in Appendix B Research Protocol and in Appendix C Amendments to Research Protocol.
- 1.22 "Research Committee" shall have the meaning set forth in Article 3.
- 1.23 "Research Team" shall mean all the investigators set forth in Article 3 and any other investigators, research employees and students involved in the Research Project.
- 1.24 "Result(s)" shall mean any and all result(s) arising from work done in laboratories of the Academic Institutions pursuant to the Research Project, whether or not these constitute Intellectual Property.
- 1.25 "Steering Committee" shall have the meaning set forth in Article 3.

2. ABOUT THE RESEARCH PROJECT

2.1 Background

The Research Team submitted the idea of the Research Project in December 2002 to the Research Committee. The Board was informed of the Research Project at the December 2002 Board meeting. In January 2003, the Executive Director of the CBHSSJB submitted a letter of commitment to support the Project. The Research Committee supported the Research Team's successful application for external funding with the Canadian Institutes of Health Research, through the New Emerging Team funding program of the Institute of Aboriginal Health. The project was approved at the end of April 2003. Dr. Alain Cuerrier made a presentation on the project in July 2003 to the joint boards of the CBHSSJB and the Grand Council of the Crees (Eeyou Istchee)/Cree Regional Authority. The Research Project was approved by the Board of the CBHSSJB in March 2004.

2.2 Description of the Research Project

The Research Project is fully described in the Research Protocol and its amendment(s) in APPENDIX B RESEARCH PROTOCOL AND C AMENDMENTS TO RESEARCH PROTOCOL. These Protocols are confidential.

- Academic Institutions: If the Research Team wishes to amend the Research Protocol, such amendments must first be approved in writing by the Research Committee and the Participating Cree First Nations. Also, new Researchers and Academic Institutions may be added to the Research Project if a) this is approved in writing by the CBHSSJB and the Participating Cree First Nations; and b) if the new Academic Institution becomes an additional Party to this Agreement by signing a Letter of Agreement in which it agrees to be bound by this Agreement and the new Researcher signs an Undertaking in the form of the Undertaking signed by the present Researchers. Such Letter of Agreement and Undertaking shall be included in Appendix F Letters OF AGREEMENT.
- 2.2.2 <u>Summary of the Research:</u> Some Traditional plant medicines may have properties that would be useful for diabetes prevention and to help regulate blood sugars and/or to promote insulin secretion.
 - a) The Research Team will work in partnership with the Elders and Healers, who are specialists in traditional medicines. The combination of the traditional and modern scientific knowledge will identify and validate which elements of traditional medicine have a pharmacological and nutritional basis which are effective in treating diabetes-related diseases, and how toxicological or other risks can be minimized.
 - b) The Research Team and the Elders and Healers shall identify a number of plants. The plants that will be chosen are those that are used by the Elders and Healers to prepare medicine for one or more symptoms also associated with diabetes and that are generally regarded as safe by both the Elders and Healers and the botanists of the Research Team.
 - c) Appropriate extracts of the plants will be prepared according to guidelines developed by the Elders and Healers and the Research Team. The plants will be analysed to identify their active ingredients so that standardised preparations can be made.
 - d) At the same time, the anti-diabetic potential of the plant extracts will be studied both with animals that have diabetes-like conditions and with pancreatic and insulin-sensitive tissues such as liver, muscle and adipose tissue.

- e) Studies with Iiyiyiuch may involve a small qualitative observational study with blood test results and possibly a randomised control trial in the later years of the Research Project.
- f) Within the CBHSSJB, the study will promote collaboration to explore ways to integrate traditional medicines into the diabetes clinics. On the longer term, the Research Project's objective is that there will be a greater acceptance of inclusion of both modern and traditional medicine in global health care for diabetes and that this would lead to a more effective and culturally appropriate care for the Iiyiyiuch and possibly serve as a model for other First Nations.
- g) The entire Research Project will be carried out in a manner respectful of Iiyiyiu culture and attentive to Iiyiyiu Traditional Knowledge.
- 2.2.3 <u>Location of the research:</u> The field component of this Research Project will take place in the community and traditional territory of each Participating Cree First Nation.

The Herbarium will be prepared at the Marie-Victorin Herbarium in the Montréal Botanical Garden, under the control of MONTRÉAL.

The phytochemical analysis of the plants will be conducted at OTTAWA. The analysis of the plants for their anti-oxidant potential will take place at MCGILL. The animal and tissue culture studies for this Research Project will be carried out primarily at MONTRÉAL and CHUM.

- 2.3 Approvals, and Participating Cree First Nations and additional Cree Participating Cree First Nations
 - 2.3.1 Participating Cree First Nations: The Council of the Cree Nation of Mistissini (Resolution number 2005-319A dated September 6, 2005) and the Council of the Whapmagoostui First Nation (Resolution number 07-011 dated February 20, 2007) have approved the Research Project. Their resolutions are included in APPENDIX E PARTICIPATING CREE FIRST NATIONS' RESOLUTIONS.
 - 2.3.2 Withdrawal of a Participating Cree First Nation: The Parties agree that the Participating Cree First Nations individually and collectively have a right to withdraw their participation in (and to refuse that their Confidential Information or the Iyiyiu Plants be used for) one or several phases of the Research Project, which are described in Appendixes B and C. Such a withdrawal shall be decided by Council resolution, in consultation with the Elders and Healers of the community and following a recommendation of the community research committee of the Participating Cree First Nation (if any). The reasons for the decision must be described in writing to the other Parties. The Parties agree that

such a decision does not prejudice in any manner their involvement in other aspects of the Research Project or their rights under this Agreement.

- 2.3.3 Additional Participating Cree First Nations: Any other Cree First Nation may decide to become a Party to the Agreement by sending a Letter of Agreement approved by Council resolution containing its agreement to be bound and abide by all terms and conditions of this Agreement. The Letter of Agreement, shall be included in APPENDIX F LETTERS OF AGREEMENT.
- 2.3.4 Other Parties' approvals obtained: This research has been approved by the CBHSSJB (Region 18 of le Ministère de la santé et des services sociaux du Québec), the Canadian Institutes of Health Research, MCGILL, CHUM, OTTAWA, MONTRÉAL, the Research Ethics Board of MCGILL and the Animal Ethics Committee of MONTRÉAL. These approvals are annexed in APPENDIX D CBHSSJB AND OTHER APPROVALS.

2.4 Purpose of the Research Project

The purpose of this Research Project is to better understand:

- 2.4.1 How scientific knowledge can help to validate and supplement certain aspects of Iiyiyiu Traditional Knowledge.
- 2.4.2 Whether specific traditional Iiyiyiu medicines possess anti-diabetic properties that function to either lower blood glucose levels, normalize lipids, and/or help stimulate insulin production.
- 2.4.3 Whether some of these plants will also possess anti-oxidant properties.
- 2.4.4 Whether specific traditional Iiyiyiu medicines with anti-diabetic properties might be seen by the community as an acceptable dietary intervention strategy, along with conventional therapies, for the management and prevention of diabetes and its complications that is in harmony with their world view.
- 2.4.5 The extent to which the results of this project may be useful across many areas of northern Canada, and other northern countries, because of the wide distribution of boreal and subarctic plants.
- 2.4.6 How contributing to the knowledge of traditional medicines in northern Quebec will help to reinforce this aspect of Iiyiyiu Traditional Knowledge.

- 2.4.7 The process for developing an effective and ethical collaboration between specialists in traditional science and modern science.
- 2.4.8 The process for developing guidelines from this collaboration to assist future collaborations in northern Quebec and elsewhere.
- 2.4.9 The extent to which a project of this type can help to stimulate interest in this area among the youth.
- 2.4.10 The extent to which a project of this type can help to reaffirm and enhance the role of traditional concepts of health in the communities.
- 2.4.11 The preferred ways to consume traditional medicines.

3. CONDUCTING THE RESEARCH

3.1 Research Team, Research Committee and Steering Committee

The Researchers, under the direction of the Principal Investigator, are responsible for carrying out the project within the budget limits set out in each of the grants received for the Research Project by the Parties and described in Section 7 and with the collaboration of the Research Committee and the project Steering Committee as described below.

3.1.1 Researchers:

APPENDIX A RESEARCHERS AND COMMITTEES contains a list of the Researchers participating in the Research Project as well as their complete coordinates and the duration of their participation. They have provided the Parties with an Undertaking to comply with this Agreement which includes a declaration concerning conflicts of interest. A model Undertaking and the signed Undertakings are appended to this Agreement.

Contact person for the Research Team:
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Department of Pharmacology, Faculty of Medicine
Université de Montréal
P.O. Box 6128, Downtown Postal Station
Montreal, Quebec H3C 317
Tel: (514) 343-6590 Fax: (514) 343-2291
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In addition to the Researchers, a number of the Academic Institutions' employees, consultants and associates including graduate and undergraduate students will be participating in the Research Project. Every year, upon request, the Researchers will provide the CBHSSJB with the names of their employees, consultants, students and

associates who shall be participating in the Research Project in the following year, to be confirmed at the end of the year. The Academic Institutions agree to ensure that such persons are informed of the obligations contained in the agreement, in particular with respect to confidentiality, and that they sign a commitment of the type included in APPENDIX A prior to participating in the Research Project. The signed commitment shall be sent to the other parties (electronically or otherwise). The Academic Institutions agree that they are responsible for any failure on the part of such persons in this regard. Other people participating on a very temporary basis in the Research Project (for example if they are present at a meeting of Research Project) may be asked to sign a confidentiality agreement of the type listed in APPENDIX A.

3.1.2 Research Committee of the CBHSSJB:

The Research Committee is a permanent internal committee of the CBHSSJB which is responsible for establishing and reviewing research policy and procedures; approving research collaborations, research protocols and research agreements; as well as reviewing research implementation and dissemination plans with specific focus on developing knowledge transfer methods and strategies for the region. Until an Ethics Committee is constituted, the Research Committee also maintains an overview of the research and public health surveillance ethics for the CBHSSJB. Its members are listed at APPENDIX A RESEARCH TEAM AND COMMITTEES.

3.1.3 Steering Committee for the Project:

The Steering Committee is a temporary ad hoc group composed of certain members of the Research Team, members of the CBHSSJB as well as of the Participating Cree First Nations and other entities. It was created specifically for this Research Project as a forum for the different interested parties to be able to exchange relating to the Research Project and provide information concerning the progress of the research and direction and counselling in respect of this Research Project. Its members are listed at APPENDIX A RESEARCH TEAM AND COMMITTEES.

As other Cree First Nations join the Research Project, the Steering Committee will be enlarged to include representatives from each additional Band Council and /or administration and from the local Elders' Council of that Cree First Nation.

3.1.4 Each Participating Cree First Nation may wish to involve its community research committee or any similar committee, if such exists, to take decisions at the community level or make recommendations to its Council with regards to the Project. As required, the Participating Cree First Nations will recommend qualified community members who can be hired as assistants by any

Academic Institution and paid from the Research Project budget as planned and in accordance with the budgeted amount granted by the CIHR. To the extent possible, the Research Team will train these local research assistants in basic techniques of data collection.

3.2 Methods to be used

The Research Team shall be responsible for the performance of activities described in Appendix B and C by the Elders and Healers, the Researchers, student assistants or Iiyiyiu assistants, as the case may be. Some of those activities may include the following:

3.2.1 Preparatory work:

- Formal invitation from Participating Cree First Nations.
- Comprehensive review of existing literature concerning potential anti-diabetic plants of northern Quebec.
- Preliminary field work in the summer of 2003.
- Community workshop to present the overall project summer 2004.

3.2.2 Ethnobotanical fieldwork.

- Recorded interviews with Iiyiyiu Healers and Elders from each Participating Cree First Nation with the help of a broad-openended questionnaire for assessing medicinal plants related to the symptomatology of Type 2 diabetes. During the first interview, special attention will be paid to Iiyiyiu plant names and remedy preparations.
- Identification and assessment of the plants with the local team (Healers, Elders, Researchers and student assistants).
- Collection of plant specimens.
- Survey of preferred practices for administering standardized preparations of targeted remedies.

3.2.3 Laboratory work:

- Preparation of standardized medicines from the plants in conformity with the traditional recommendations of the Elders and Healers as well as standard phytomedicine procedures.
- Feeding studies, including of two types of animals with diabetestype conditions (genetic model and nutritionally-induced model) with potential anti-diabetic liyiyiu plants identified during the ethnobotanical fieldwork compared with fenugreek and conventional anti-diabetic medicines.
- Study of pancreatic, liver, adipose and muscle tissue from the animals for insulin secretion, insulin responsiveness, and signal transduction, respectively.

- Study of cells or cell lines (including pancreatic, liver, adipose and muscle cells) in culture for insulin secretion, insulin responsiveness, signal transduction and protection against cell death.
- Characterization and standardization of the active chemical properties of the selected Iiyiyiu medicine plants.
- Study of the anti-oxidant properties of the selected Iiyiyiu medicine plants.

3.2.4 Community-based work:

- Consultation with Elders and Healers, experts and a review of published literature on aspects of traditional and contemporary health concepts, dietary practices and traditional medicine practices.
- Consumption survey based on a seven-day frequency recall undertaken with a randomly selected cross-section of the adults in the community (n ≥ 50). The survey will focus on specific practices that incorporate traditional dietary supplements, teas, and methods of food preparation as well as food intake. A supplementary questionnaire will elucidate patterns of diet, lifestyle and health that would most support interventions with either traditional manners of preparation or standardized extracts.
- Focus groups with participants of various ages will be brought together to discuss most acceptable modes of incorporating dietary supplements into contemporary lifestyle.

3.2.5 Training and linkage:

- Training of Iiyiyiu interpreters/trainees in both traditional ways and modern ethnobotanical methods.
- Training of graduate students and postdoctoral fellows.
- Linkage to Network Environments for Aboriginal Health Research (NEAHR), Aboriginal Capacity and Developmental Research Environment (ACADRE), the pan-Canadian Natural Health Product Research Network, Montreal Diabetes Center and other groups and experts.
- Education within the region through the specimen samples prepared for the Cultural Institute and the schools.

3.3 Translation

The Research Team will pay for all costs of translation in order to carry out field interviews that need to be done in Cree, unless costs of translation exceed the budgeted amount granted by the CIHR, and in which case the additional costs of translation will be paid by the CBHSSJB, with assistance or not from other Participating Cree First Nations.

3.4 Consent of Elders and Healers and other community members

- 3.4.1 The model Consent letter of participation signed by the Elders and Healers which indicates their consent to participating in the Research Project, as well as any additional consent forms signed, is included in APPENDIX G CONSENT LETTER OF PARTICIPATION.
- 3.4.2 All consent forms used to solicit the participation of community members should be written in plain English. The Researcher provides a consent form approved by the Research Ethics Board of the concerned Academic Institution. It is reviewed by the Research Committee. If it is already in plain English, it shall be used. If not, a plain English version of the consent is prepared by the Research Committee, and such version is the one used.
- 3.4.3 Consent forms will include the name, address and phone number of the research interviewer and the name and phone number of the community contact person. They will also include the name and phone number of the Public Health Research Office as the contact for questions concerning the project after its completion. They will also clearly describe the Research Project, the potential risks and benefits, the methodology used, how the information provided by the Elders and Healers will be used and to whom it will be transferred (for example if kept confidential or made public), the relevant intellectual property and privacy issues, as well as any other important aspect of the Project.
- 3.4.4 The consent form will be read by the interviewer or research assistant to each participant, in Cree or in English, as requested by the participant. For each participant, two copies of the consent form will be made and one will be signed by him. The Researcher responsible for interviews, Dr. Alain Cuerrier, shall keep the copy signed and the participant will keep the other copy.
- 3.4.5 The Researcher for each specific section of the Research Project will ensure the safekeeping of the signed consent forms for his or her section of the Research Project.

4. CONFIDENTIALITY

4.1 Confidentiality

The Confidential Information and the Results remain confidential until all the concerned Parties have decided to make it public information as set out below. To facilitate this, any person obtaining Confidential Information or Results through their presence at a meeting or otherwise shall sign, prior to obtaining the information, a confidentiality undertaking of the type set out in APPENDIX A.

4.2 Access to and use of the Confidential Information

- 4.2.1 The Academic Institutions shall use any Confidential Information and the Iiyiyiu Plants and extracts solely as described in the Research Protocol set out in APPENDIXES B AND C.
- 4.2.2 Each Academic Institution agrees to restrict access to the Confidential Information and to the Iiyiyiu Plants and extracts to its Researchers, employees and associates participating in this Research Project, including graduate students and undergraduate students. It may also provide Iiyiyiu Plants and extracts to specific subcontractors for specialized testing on the condition that the samples are denominalized.
- 4.2.3 Subject to the provisions of paragraph 4.2.2 hereinabove, the Parties shall obtain the consent of any Provider in writing before disclosing any such Provider's Confidential Information to any person, agency, media or organisation. The Parties shall also obtain consent of the Concerned Participating Cree First Nations prior to disclosing the names of the Iiyiyiu Plants. Prior to giving authorization, the Participating Cree First Nations shall make efforts to consult their respective Elders and Healers.
- 4.2.4 Consent is not required if the Iiyiyiu Confidential Information has already been published by the Research Team within the context of the Research Project and in accordance to this Agreement, unless such disclosure is to the mass media or if the disclosure could have a significant impact on the Participating Cree First Nations.
- 4.2.5 Each Academic Institutions agrees that it will not knowingly take any steps that could reasonably result in the commercialisation of the liyiyiu Confidential Information or Iiyiyiu Plants or extracts without prior written authorization for such from the concerned Participating Cree First Nations, who shall, before giving such consent, consult their respective Elders and Healers. To that end, the Academic Institutions agree that they shall consult the Principal Investigator and the Concerned Participating Cree First Nations if they are asked by anyone associated or not associated with the Research Project to participate in any action which could result in the commercialisation of an Iiyiyiu Plant or plant extract. The Principal Investigator and the Concerned Participating Cree First Nations will help the Academic Institutions to determine whether the requesting person's project has used either directly or indirectly Iiyiyiu Confidential Information.

4.3 Disclosure of Results in the context of scientific publications

Any disclosure to third parties of Results, such as in public reports, scientific publications, abstracts, presentations or other similar documents, must follow the

process set out in APPENDIX H WORKING PROCEDURE to ensure Confidential Information may be extracted if one or several Parties request it. The Parties agree that the Working Procedure may be amended by decision of the Steering Committee, if, following a discussion in that regard during a Steering Committee meeting, the representative of the CBHSSJB and a majority of the representatives of the Participating Cree First Nations (as set out in Appendix H) and a majority of the Academic Researchers sitting on the Steering Committee, provide their consent in writing. Any major amendment to the Working Procedure shall be revised by the appropriate authorized representative of each of the Academic Institutions. The amended Working procedure shall be appended to this Agreement.

4.4 Disclosure of Results to the public at large and non-commercialisation

- 4.4.1 The Academic Institutions, the CBHSSJB and Concerned Participating Cree First Nations shall each obtain the consent of the others in writing before discussing any unpublished details of the Research Project and its Results with any person or organisation, the media or with non-scientific, public forums outside of the region. In the case of the Research Team, the consent shall be given by the Researcher(s) having participated in the studies from which the Results were derived.
- 4.4.2 The hereinabove consent is not necessary if the concerned Confidential Information or Results has already been published by the Research Team within the context of the Research Project and in accordance with this Agreement, unless such disclosure is a) to the media, in which case the consent of the Researcher(s) having participated in the studies from which are derived the Results, the CBHSSJB and the Concerned Participating Cree First Nations is necessary or b) if the disclosure could have a significant impact on the Concerned Participating Cree First Nations, in which case the consent of the Concerned Participating Cree First Nation is necessary.
- 4.4.3 No steps that could result in the commercialisation of the Results will be done without the prior written authorization from the Researcher(s) and the appropriate authorized official of the Academic Institutions involved in the development of the Results, the CHBSSJB and the Participating Cree First Nations, which shall consult with the Elders and Healers before granting any such authorization.

4.5 Exceptions concerning confidentiality

Information disclosed by a Provider shall not be considered "Confidential Information" for the purposes of this Agreement if and when it:

a) is made pursuant to an order by judicial or administrative authority

requiring the Recipient to disclose any or all of the Confidential Information disclosed to it by the Provider, provided however that the Recipient shall promptly notify the Provider and allow the Provider reasonable time to oppose such order before disclosing any of the Confidential Information disclosed to it by the Provider;

- is published or becomes available to the general public other than through a breach of this Agreement; for greater certainty, the Parties agree that Iiyiyiu Traditional Knowledge does not fall within this exception unless it has been published in the context of this Project and in compliance with this Agreement;
- c) is obtained by the Recipient from a third party not under a confidentiality obligation and having a valid right to disclose such information; is independently developed by employees, agents or consultants of the Recipient who had no knowledge of or access to the Confidential Information disclosed to it by the Provider as evidenced by the Recipient's business records; or was possessed by the Recipient prior to receipt of the information from the Provider, other than through prior disclosure by the Provider, as evidenced by the Recipient's business records.

4.6 Privacy of Data Providers

- 4.6.1 No personal information relating to members of the Participating Cree First Nations providing Data can be disclosed unless their prior informed written consent is obtained from each concerned member.
- 4.6.2 During the Research Project, the name of each Provider will be held on a master sheet and may only be associated with the individual Data records through a code.
- 4.6.3 During the Research Project, only number codes will identify Participating Cree First Nation members on Data records.
- 4.6.4 The Provider must give written consent to have his or her name used in any public communication, report or publication.
- 4.6.5 Each concerned Participating Cree First Nations, through its representative on the Steering Committee, will give written approval for the use of its name in any public communication, report or publication.
- 4.6.6 At the termination of the Research Project, the Academic Institutions must return the master sheets that link Data records to the names of Providers to the concerned Participating Cree First Nations. Should the Academic Institutions wish to keep a copy of these, they must

enter into a subsequent Research Agreement with the concerned Participating Cree First Nations.

5. INTERPRETATION OF DATA, REPORTING AND DATA MANAGEMENT

5.1 Costs of dissemination of information related to the Research Project

Unless other arrangements have been made with the Research Committee, the cost of the dissemination of information related to the Research Project will be included in the costs of the Research Project, unless the costs of dissemination exceed the budgeted amount granted by the CIHR, in which case the additional costs for dissemination will be paid by the CBHSSJB.

5.2 Progress reports and queries

The Research Team shall provide the other members of the Steering Committee with progress reports every month, or, if such is not reasonably practicable, at least every four months, indicating the nature of the Results and whether any Intellectual Property has been or is being developed (including publications). During the course of the Research Project, each Researcher will make his or her best efforts to be available to respond to particular questions that may arise from members of the Participating Cree First Nations and from the Steering Committee. The Elders and Healers will be kept informed of the Results by way of the review of publications as described in section 5.4 as well as by a semi-annual report on the Results which shall be translated into Cree.

5.3 Publications and collaboration between the Iiyiyiuch and the Research Team concerning interpretation of Data

Publishing Results in peer-reviewed scientific journals is important to the Research Team as this allows them to contribute to modern scientific knowledge and have their knowledge acquire legitimacy, recognition and respect in the scientific community. Also, publication of livijui Traditional Knowledge in scientific journals, if accepted by the Concerned Participating Cree First Nations according to the process set out in APPENDIX H, will contribute to the recognition of such knowledge in the medical, national and international communities.

5.4 Review of publications and other related documents

Any disclosure to third parties of Results, such as in public reports, scientific publications, abstracts, presentations or other similar documents, must follow the process outlined in APPENDIX H - WORKING PROCEDURE REGARDING REVIEW OF PUBLICATIONS, unless the document does not relate to Iiyiyiu Traditional Knowledge or to an Iiyiyiu Plant or extract. In such a case, the Research Team must provide the representatives of the Participating Cree First Nations and of the CBHSSJB the

proposed publication and a brief explanation describing the reason why the publication should not be submitted to the review process.

As described in more detail in Appendix H, which sets out the precise procedure and timelines to follow, this review procedure aims to achieve a number of objectives:

- a) <u>Collaboration concerning interpretation:</u> Because this Research Project involves a contribution of knowledge from both Elders and Healers and the Research Team, the procedure provides for discussions concerning the Results and the proposed publications as well as an obligation on the part of the member of the Research Team that wishes to publish, to attempt to integrate the comments made by the Iiyiyiuch.
- b) Extraction of Confidential Information: If the publication, abstract or similar document contains Confidential Information (such as Iiyiyiu Traditional Knowledge) that some Parties do not wish to be disclosed to third parties, the Parties must negotiate a version of the disclosure which is acceptable to all.
- c) Recognition of Iiyiyiu contribution to the publication: The procedure provides for the appropriate recognition of the contribution of Elders and Healers in the form of authorship or an acknowledgement, depending on the circumstances and the wishes of the Elders and Healers.

The Parties agree that consent of all Parties is not necessary to amend the Working Procedure. It may be amended by decision of the Steering Committee, if the representative of the CBHSSJB and a majority of the representatives of the Participating Cree First Nations and a majority of the Academic Researchers sitting on the Steering Committee provide their consent in writing. Any major amendment to the Working Procedure shall be revised by the appropriate authorized representative of each of the Academic Institutions. The amended Working procedure shall be appended to this Agreement.

5.5 Preparation of plain language popular reports and popular documents

For each major scientific publication relating to the Research Project, the Research Team will present the findings of the publication to the Participating Cree First Nations and the CBHSSJB as a plain language report prepared for wide distribution within the region. The collections of plant specimens made for the Aanischaaukamikw (Cree Cultural Institute) and the Iiyiyiu schools will be considered popular documents relating to the Research Project. The Research Office of the CBHSSJB will be responsible for disseminating popular reports in the region.

5.6 Communicating the results in the region

When the Research Team is ready to begin communicating the Results, it will discuss with the Steering Committee and the Research Office of the CBHSSJB how best to disseminate the Results within the region, whether by radio broadcasts, community

meetings and/or articles in The Nation and local papers. The Research Team will be welcome to consult with the CBHSSJB Cree-speaking communication specialists to develop a dissemination plan.

5.7 Storing of Data and other materials during the Research Project

- 5.7.1 The Herbarium (e.g. the ethnobotanical samples) will be stored at the Marie-Victorin Herbarium in the Montréal Botanical Garden, under the control of MONTRÉAL.
- 5.7.2 During the project, the Data and the Iiyiyiu Plants collected with the help of the Elders and Healers through ethnobotanical field work will be kept in a secure location at the Marie-Victorin Herbarium in the Montréal Botanical Garden under the control of MONTRÉAL and at MCGILL in paper, digital and photographic formats as applicable. A copy of the Data obtained from each Participating Cree First Nation will be provided to that Participating Cree First Nation.
- 5.7.3 Project materials (other than the Data, Iiyiyiu Plants, Results and the Herbarium) obtained through laboratory work, such as but not limited to plant extracts and fractions thereof, lab books, analytical machine outputs, charts, graphs, electronic data sets (e.g. excel sheets including raw and transformed scientific data) and illustrations will be kept respectively at MONTRÉAL, MCGILL, OTTAWA and CHUM, if applicable.
- 5.7.4 The Academic Institutions shall take all reasonable precautions, including using adequate technology, to ensure the confidentiality, security and appropriate conservation of the Data and the Iiyiyiu Plants. To the extent the Data and the Iiyiyiu Plants are no longer needed for the Research Project, they shall be returned to the Concerned Participating Cree First Nations.

5.8 Disposal of the Data

5.8.1 At the end of the Research Project, subject to Section 5.8.4, all Data and the Iiyiyiu Plants shall be returned to the respective Participating Cree First Nations through the Research Office of the CBHSSJB; The Project materials (as described in Section 5.7.3) will remain in the respective Academic Institutions, but they shall not be used without obtaining the prior written consent of the other Parties and, in the case of other Academic Institutions, of only those involved in the development of the Project materials. Such authorization is not necessary if such Project materials relate to the Researchers' experimental tools (which were developed or applied in the context of the Research Project, but are not based on Iiyiyiu Traditional Knowledge, Iiyiyiu Plants or extracts).

- 5.8.2 Later, insofar as new agreements are entered into for these purposes, the Research Team will be available to assist the Participating Cree First Nations and the CBHSSJB to use this returned Data for purposes beyond the objectives of the Research Project;
- 5.8.3 The Participating Cree First Nations or any other authorized depository of the master list linking the Providers to Data, may according to such terms as the Parties deem appropriate, grant access to such list upon the written request by a Party or its representatives or by the Montréal Botanical Garden or following any agreement in furtherance of Section 8.4;
- 5.8.4 The Herbarium, notwithstanding Section 6, will be permanently stored at the Marie Victorin Herbarium in the Montréal Botanical Garden;
- 5.8.5 Aanischaaukamikw (Cree Cultural Institute), the CBHSSJB as well as every community school in Iiyiyiu Aschii shall be provided with a copy of the Herbarium.

6. INTELLECTUAL PROPERTY AND TRADITIONAL KNOWLEDGE

6.1 liyiyiu guardianship of Traditional Knowledge

Iiyiyiu Traditional Knowledge, its creation, discovery, development and transmission and every matter relating thereto, forming part thereof and arising therefrom are vested in the Iiyiyiu Nation and the Iiyiyiuch are the sole guardians of this knowledge which is held for the benefit and use of the Iiyiyiuch.

6.2 Representation

The Iiyiyiuch of each Participating Cree First Nation are, for the purposes of this Agreement, represented by their respective Participating Cree First Nation.

6.3 License

The Participating Cree First Nations hereby grant to the Academic Institutions a non-exclusive licence to use for the duration of the Research Project the Iiyiyiu Traditional Knowledge solely for the purposes of:

- a) the Academic Researchers' non-commercial research relating to diabetes prevention, the regulation of blood sugars and the promotion of insulin secretion, as more fully described in the Research Protocol and its amendments attached in APPENDIXES B AND C; and
- b) publication, subject to the conditions set out in sections 4 on Confidentiality and 5 concerning the Interpretation of Data.

For greater certainty, the scope of this licence is not broadened in any way if the liyiyiu Traditional Knowledge is made available to the general public through publication or otherwise.

6.4 Joint Intellectual Property

- 6.4.1 Any Joint Intellectual Property is deemed to be created, discovered or developed by using Iiyiyiu Traditional Knowledge. Therefore, the Participating Cree First Nations, for the benefit of the liviyiuch of their respective communities, shall be undivided co-owners of the concerned Joint Intellectual Property, together with the CBHSSJB and the Academic Institution(s) whose Researchers contributed as inventors to the creation, discovery or development of the concerned Joint Intellectual Property (sharing with their Academic Researchers if applicable under their internal policy). The Academic Institutions other than that of the inventor(s) will also be offered co-ownership because the Parties consider that this Research Project is the fruit of collaboration between all Parties. These Academic Institutions shall not however be entitled to prevent an application to register any Joint Intellectual Property if such is the decision taken by the inventor's Academic Institution, the CBHSSJB and the Participating Cree First Nations. If an Academic Institution offered co-ownership is not interested in commercializing the Joint Intellectual Property, it shall not become a co-owner. Also, any of the Parties may decide at any time to renounce its co-ownership by sending a letter to that effect to the other Parties. In this case, that Party no longer has any of the rights or obligations associated with ownership, such as the right to consent to commercialization or to own shares in any corporation or the obligation to pay associated costs.
- 6.4.2 The Parties agree not to disclose the Joint Intellectual Property to any person, agency, media or organisation without prior authorisation in writing from the other co-owners as set out in section 6.4.1. The Participating Cree First Nations shall consult their respective Elders and Healers. One of the objectives of this sub-section is to ensure no disclosure could preclude the filing of a patent application or the issuance of a valid patent in Canada or in any other jurisdiction. Consequently, any scientific reporting, as referred to in Sections 4.3 and 5.4, shall be reviewed by the Parties to ensure compliance herewith.
- 6.4.3 Notwithstanding section 6.4.1, the Joint Intellectual Property does not include the Researchers' experimental tools, developed or applied in the context of the Research Project but not based on Iiyiyiu Traditional Knowledge, Iiyiyiu Plants or extracts. The Researchers that did not collaborate in the development of these tools and their Academic Institution are required to obtain from the

Researchers and the Academic Institution that developed them the authorization to disclose to third parties these tools or to use them in other projects. Researchers that collaborated in the development of a tool are not required to obtain any authorization to do same.

6.4.4 Every month, or if such is not reasonably practicable at least every four months, the Research Team shall provide the Steering Committee with information regarding any Joint Intellectual Property developed, including publications (copyright).

6.5 Joint Intellectual Property Corporation

- 6.5.1 No commercialisation and no assignment of any Joint Intellectual Property or any process or product derived from such shall be carried out anywhere without the prior written authorization of its co-owners as set out in Section 6.4.1. The Participating Cree First Nations, shall consult with the Elders and Healers before granting any such authorization.
- 6.5.2 No application to protect any Joint Intellectual Property through patent or otherwise shall be filed in any jurisdiction without the prior written authorization of its co-owners as set out in Section 6.4.1. The Participating Cree First Nations shall consult with the Elders and Healers before granting any such authorization. All concerned Academic Institutions shall provide their full cooperation to achieve patent application.
- 6.5.3 The objective of the Research Project is not to commercialize the Joint Intellectual Property. Nonetheless, the Parties may determine that the registration of Joint Intellectual Property is desired. In this case, and unless the Parties decide otherwise by way of a new agreement to address all issues related to the registration and use of the Joint Intellectual Property in question, ownership in any patent or patent application for registration or in any registration of Joint Intellectual Property filed by any Party to this Agreement shall be assigned to a corporation to be created for the purpose of the management and commercial use of the Joint Intellectual Property ("Corporation"). Said Corporation shall be the sole proprietor of the Joint Intellectual Property. Nonetheless the Academic Institutions, the Participating Cree First Nations and the CBHSSJB shall retain the right to freely use the Results for teaching purposes as set out in Section 8.5 c.
- 6.5.4 All co-owners as set out in Section 6.4.1 shall own shares in the Corporation. The Participating Cree First Nations and the CBHSSJB shall collectively own 51% of the shares of the same category of the share capital of the Corporation, each share bearing a voting right. The Participating Cree First Nations hold all such shares for the

benefit of their members. The Academic Institutions shall collectively own 49% of the same shares of the Corporation. In the event of new Parties joining the Research Agreement, the 51/49 proportion is maintained. The Parties hereto agree to execute all necessary documentation to give full force and effect to this provision. Unless otherwise agreed, the co-owners shall contribute proportionally to the costs relating to the Corporation based on the number of shares they own.

6.5.5 A co-owner has the right to transfer its shares in the Corporation to an entity of which it owns more than the majority of the shares. Thirty days prior to doing so however, it shall have a) informed in writing the other co-owners of its intent and of the exact relationship between itself and the controlled entity and b) provided them with a commitment from the transferree that it will respect this Final Research Agreement and any other agreement agreed to concerning the Joint Intellectual Property.

7. FINANCING OF THE PROJECT

In addition to the in-kind contributions of the CBHSSJB, the Participating Cree First Nations, MONTRÉAL, CHUM, OTTAWA and MCGILL, this project is being supported by the following direct research grants known at this time:

- CIHR, Grant of \$300,000 a year for three years agreed by the end of April 2003 under the CIHR Aboriginal People's Health's Institute
- CIHR, Grant of approximately \$935,000 a year for the period between April 1, 2006 to March 31, 2011 under the CIHR Aboriginal People's Health's Institute
- CBHSSJB and Ministère de la Santé et des Services Sociaux Grant of \$30,000 under the Public Health Research Grants Programme.

The Research Team agrees to inform the Research Committee of all subsequent grants received to carry out the Research Project so they can be appended to this Agreement at APPENDIX C.

8. TERM AND TERMINATION OF THE RESEARCH PROJECT AND OF THE AGREEMENT

8.1 Term and Normal termination Date of the Research Project and of the Agreement

This Agreement is effective since April 1st, 2003 (the "Effective Date"). The Research Project will end on March 31, 2011 and the Agreement shall be terminated

on March 31, 2012 (the "Normal Termination Date") in order to provide time to the Parties to complete the preparation and review of the scientific publications. The Parties may agree to extend the termination date through a written undertaking for that purpose.

8.2 Extending the relationship between the Parties

Upon normal termination of this Agreement, any further agreement in relation to the Data and the Results shall comply with the terms and conditions of this Agreement where reasonably applicable and with the Tri-council Policy Statement on research with human subjects such as amended from time to time.

8.3 Exceptional termination of the Research Project or of the Agreement

- 8.3.1 Should disagreement between some or all of the Parties arise over the performance of the Research Project, the concerned Parties shall make all reasonable efforts to resolve the dispute amicably and in a respectful manner. If resolution is not possible, the concerned Parties will seek the advice of a mediator chosen by all of them; in the event that they cannot agree upon a mediator, they shall each nominate one individual and those nominees shall select another individual who shall act as the sole mediator. If there are more than two Parties involved in the dispute, those Parties having similar interests shall nominate only one nominee. The Parties shall make all reasonable efforts to follow the advice provided by the mediator to resolve the dispute.
- 8.3.2 If a member of the Research Team has violated the policies relating to research ethics of their own Academic Institution or of the Tri-Council, including but not limited to research involving human subjects, or if the Participating Cree First Nation(s) feels that its cultural integrity is being threatened by the Research Project, the CBHSSJB and the Participating Cree First Nation(s) may withdraw their participation in this Research Project. In both cases, the reasons for the withdrawal must be adequately described in writing by the withdrawing Party and the mediation process set out in section 8.3.1 shall be followed. If resolution is not possible, the Agreement shall be terminated upon receipt by the Academic Institutions of a notice in writing: in the case of the CBHSSJB, by the Executive Director pursuant to a resolution of the Board or the Executive Committee acting upon the recommendation of the Research Committee; or, in the case of a Participating Cree First Nation, by the Chief pursuant to a council resolution and subsequent to consultation with its Elders and Healers. Depending on the circumstances, the CBHSSJB and the Participating Cree First Nations could decide to postpone the termination of the Agreement in order to allow a Researcher or a student to finalize a publication or a thesis despite their withdrawal.

In such a case this Agreement would remain in effect until the publication or the final acceptance of the thesis.

8.3.3 A Party is in default if one or another of its obligations set out in this Agreement is not carried out when required under this Agreement and the defaulting Party has not remedied this default within thirty (30) days of receiving a written notice from any non-defaulting Party. Any non-defaulting Party has the right to terminate the Agreement in respect of the defaulting Party without further notice if the default is particularly serious, for example, if the defaulting Party has taken steps to commercialize, register or disclose the Confidential Information, the Results or the Joint Intellectual Property without the consent of the required Parties as required by sections 4, 5 and 6 of this Agreement; in other cases, the Parties shall attempt to resolve the dispute in the manner set out in section 8.3.1 If such resolution is impossible, then upon a 30-day prior written notice by one of the non-defaulting Parties, the Agreement shall be terminated for the defaulting Party.

8.4 Incomplete Research Project

- 8.4.1 If the Research Project has not been completed by the Normal Termination Date, and if the Research Team has not notified the Research Committee that they will require an extension of the Normal Termination Date, provided that the CIHR also grants an extension, the Participating Cree First Nations may require the Academic Institutions to return the Data to them. The intent of this provision shall not be construed, in any way, as restricting the intellectual freedom of the Researchers, but rather as permitting the Participating Cree First Nations and the Research Committee to redress the ethical implications of an incomplete study for the people of the Iiyiyiu Nation of Iiyiyiu Aschii.
- 8.4.2 Notwithstanding the foregoing, the Parties acknowledge that due to the nature of scientific research, some of the experiments planned may not be completed even if the Parties have made all the necessary efforts to properly execute their tasks under this Research Project.

8.5 Effects of termination

Upon termination of the Agreement, the Data and the Iiyiyiu Plants will be returned in accordance with section 5.8 on Disposal of Data. in addition to those articles surviving by operation of law, the provisions of sections 4 on Confidentiality and 6 on Intellectual Property hereof shall survive the termination date indefinitely, however:

 a) the Academic Institutions shall no longer have the right to use the Data without obtaining the prior written consent of the concerned Participating Cree First Nations, and

- b) no Party may use the Joint Intellectual Property without obtaining the prior written consent of the other co-owners as set out in section 6.4.1; consent of all Parties is also required for use of the Results, although in the case of the consent of the Academic Institutions, only the consent of those involved in the development of the Results is necessary.
- c) the Academic Institutions, the Participating Cree First Nations and the CBHSSJBshall have the right to use the Results for teaching purposes without obtaining the above mentioned consent if these Results have already been published in compliance with this Agreement.

9. ETHICAL ISSUES AND BENEFITS

9.1 Ethical Approvals

The Research Team has sent the CBHSSJB a copy of the ethical approval from ethic committees of MONTRÉAL, CHUM, MCGILL and OTTAWA, as applicable. These approvals are annexed in APPENDIX D.

9.2 Ethical Considerations

The Parties wish to carry out the Research Project in the following manner in order to be respectful of the individual participants, the Participating Cree First Nations, the CBHSSJB, and the Iiyiyiu Nation as a whole. Consequently, the Parties shall act, to the best of their knowledge and in good faith, according to the following:

- Individuals' identity should not be disclosed without their consent;
- the research should be carried out in a way that makes participants feel respected;
- the Results and the Iiyiyiu Traditional Knowledge should be used in ways that are socially, morally and/or culturally respectful (as discussed during the Research Project with the Participating Cree First Nation representatives);
- the Participating Cree First Nations' right to confidentiality should be respected;
- the Results should not be reported in a way that stigmatises the Participating Cree First Nations.
- Researchers' real or perceived conflict of interests should be clearly disclosed in Appendix A.

9.3 Benefits

9.3.1 Benefits likely to be gained by the Research Team from this Research Project: The Research Team and their associates will try their best efforts to publish scientific papers in peer-reviewed journals and make presentations at scientific conferences. This will enhance their careers as research scientists and trainees in their

- respective fields and universities and help them to secure future financing for new projects.
- 9.3.2 The Research Project will also help the Research Team to develop new relationships within the region and this may help them to secure agreement for future projects in the region or with other aboriginal groups or northern communities.
- 9.3.3 Benefits likely to be gained by the CBHSSJB: The CBHSSJB expects to have greater understanding of all the issues mentioned in the section 2.4 Purpose of the Research Project. This will help in planning effective services and interventions within the region and in specific communities.
 - a) The Research Project may help the CBHSSJB to understand how to move away from a strictly conventional approach to one that is capable of incorporating the benefits of other traditions, especially Iiyiyiu traditions.
 - b) The Research Project may help the CBHSSJB Diabetes Initiative to achieve better outcomes.
 - c) The successful completion of the Research Project will enhance the CBHSSJB's reputation as an effective liviyiu, aboriginal and Quebec health services organisation.
- 9.3.4 Benefits likely to be gained by the Participating Cree First Nations and their members:
 - a) The Research Project is expected to confer greater legitimacy to and understanding of Iiyiyiu traditional medicines and Elders and Healers. It should also facilitate the transmission of knowledge to the younger generations of Iiyiyiuch.
 - b) The Research Project may help some people with diabetes or at risk of diabetes to better manage their condition or prevent the condition.
 - c) The Research Project will provide for various types of payments, including training and employment, for Participating Cree First Nations members. There will be full-time employment of at least one member of the Participating Cree First Nations and training of research assistants from each Participating Cree First Nation (at least 1 or 2, depending on size of community). Should the funds from the Research Project not be sufficient to cover the costs of hiring research assistants or to additional members of the Participating Cree First Nations, these people shall be paid for by their respective Participating Cree First Nation, if possible.

- d) Herbaria will be prepared for Aanischaaukamikw (Cree Cultural Institute) and for every community school in Iiyiyiu Aschii. The Research Team will make efforts to involve Iiyiyiu students as much possible in the creation of these herbaria as well as in any other scientific activities from which they could benefit.
- e) If directed to do so by the Elders and Healers and the Participating Cree First Nations, the Research Team will also create, with the involvement of Participating Cree First Nations members, other products relating to the Iiyiyiu Traditional Knowledge and the Results, such as books, posters and/or videos. These products shall be intended for the use of the Cree of Iiyiyiu Aschii and shall be marketed and sold in Iiyiyiu Aschii.
- f) If there is an interest and available funding, the Research Project will offer bursaries to young Iiyiyiuch interested in training as healers or as scientists.
- g) Throughout the Project, the Academic Institutions will make all reasonable efforts to purchase on a priority basis from Iiyiyiu service providers and to employ and train Iiyiyiu members as much as possible, for example when organizing meetings or creating products derived from the Research Project.

10. NOTICES

Subject to APPENDIX H, all notices, reports, payments, requests, consents, demands and other communications between the Parties, pertaining to subjects related to this Agreement, shall be in writing and shall be deemed duly given and effective (a) when actually received by mail or personal delivery, or (b) when mailed by prepaid registered or certified mail to the receiving Party at the address set forth below, or to such other address as may be later designated by written notice from any Party to the other Party on the fifth (5th) day following the deposit thereof in the mail, or (c) when transmitted by facsimile, at the facsimile of the receiving Party set forth below, on the next business day of transmittal thereof.

Or

Université de Montréal

C/o Gilles Noël Director, Research Partnership and Technology Transfer Office of Research. Services and Development Université de Montréal Postal Adress C.P. 6128, Succursale Centre-Ville Montréal (Québec) H3C 3J7

Tel: (514) 343-2307, Fax: (514) 343-2326

Civic Adress 5160, boul. Décarie, bureau 700 Montréal (Québec) H3X 2H9

Centre hospitalier de l'Université de Montréal Dr. Jacques Turgeon

The Director of Research, CHUM Pavilion Masson 3850 St. Urbain Street, Suite 8-107 Montréal, Québec, H2W 1T7, Canada Tel: (514) 890-8044

Fax: (514) 412-7186

With a copy to:
M. Serge LeBlanc
Acting Executive Director - CHUM
Pavilion Olier
3840 rue Saint-Urbain, Suite 2-127
Montréal, Québec, H2W 1T8, Canada
Tel: (514) 890-8045
Fax: (514) 412-7224

With a copy to : Dr. Jean-Louis Chiasson

McGill University
Ms Joy Gumbley, Administrator
McGill University
Office of Technology Transfer
1555 Peel Street, 11th Floor
Montreal, Quebec, Canada H3A 3L8
Phone: 514-398-7090; Fax: 514-398-1482

University of Ottawa

Office of the Vice-President Research Technology Transfer & Business Enterprise University of Ottawa 800 King Edward Ave (3042) K1N 6N5 Attn: Director, TTBE Tel: (613) 562-5842, Fax: (613) 562-5336

Cree Board of Health and Social Services of James Bay (CBHSSJB)

C/o Office of the Executive Director Chisasibi, Quebec JOM 1EO Tel: (819) 855-2844; Fax: (819) 855-2098;

Cree Nation of Mistissini

c/o Chief Mistissini, Quebec G0W 1C0

Tel: (418) 923-3461; Fax:(418) 923-3115

Whapmagoostui First Nation

c/o Chief
Whapmagoostui, Quebec
J0M 1G0
Tel: (819) 929-3384; Fax:(819) 929-3203

11. GENERAL

11.1 Headings

The section and subsection titles and headings contained in this Agreement are for convenience and reference only. Such titles and headings do not form a part of this Agreement, shall not define or limit the scope of the sections or subsections, and shall not affect the construction or interpretation of any of the sections or subsections.

11.2 Prior Agreement

An Interim Research Agreement effective on April 1, 2003 was signed in 2008 between the Researchers (as individuals) (and more specifically by Pierre Haddad, Steffany Bennett, John Thor Arnason, Alain Cuerrier, Timothy Johns, Louis Martineau, Marc Prentki, Jean-Louis Chiasson, Jean-Francois Yale, Brian Foster, Jill Torrie, David Dannenbaum, Solomon Awashish, Paul Linton and Dianne Reid), the CBHSSJB and the Participating Cree First Nations. Its content is very similar to that of this Final Research Agreement. The Interim Research Agreement remains in effect for the parties to that agreement. Nonetheless, for Parties having signed both agreements or for the Researchers having signed the Interim Research Agreement and an Undertaking to be bound to the Final Research Agreement, in the event of a conflict between the terms and conditions of this Agreement and any other terms and conditions set forth in the Interim Research Agreement, the terms and conditions of this Agreement shall prevail.

11.3 Amendments to Agreement

The terms herein stipulated may not be modified in any way without the mutual written consent of the Parties hereto.

11.4 Partial Invalidity

If any provision of this Agreement or the application of it to any person or circumstances is held to any extent invalid or unenforceable, the remainder of this

Agreement or the application of the provision to persons or circumstances other than those as to which it is held invalid or unenforceable shall not be affected.

11.5 Relief

In addition to any and all other remedies available, each Party shall be entitled to obtain relief by way of a temporary or permanent injunction to enforce the obligations of any other Party.

11.6 Governing Law and Language

This Agreement shall be governed and construed in accordance with the laws of the Province of Quebec and the laws of Canada applicable therein.

The Parties acknowledge that they accepted that this document be drawn up in English in accordance with the «James Bay and Northern Quebec Agreement» (1975).

Les Parties reconnaissent qu'elles ont accepté que la présente entente soit rédigée en anglais conformément à la «Convention de la Baie James et du Nord québécois» (1975).

11.7 Counterparts

This Agreement may be executed in counterparts, each of which shall constitute an original, but all of which when taken together shall constitute a single agreement. Signature pages may be detached from multiple separate counterparts and attached to a single counterpart so that all signature pages are attached to the same document.

IN WITNESS WHEREOF the Parties have executed this Final Research Agreement retroactively effective as of April 1, 2003, regardless of the date of execution, in 2009.

UNIVERSITÉ DE MONTRÉAL		141
By: Name Joseph Hubert Title Vice-rector, Research	Date:	12/8/2009
UNIVERSITÉ DE MONTRÉAL		W 6
By: <u>Francise Veca</u> . Name: Francise Verrier	Date:	12/8/2009
Title: Secretary General		

CENTRE HOSPITALIER DE L'UNIVERSITÉ DE MONTRÉAL	
By: Algues Jun (117) acques Turgeon, B.Pharm., Ph.D. Director of Research - CHUM	Date: 25/08/2009
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Serge LeBlanc Acting Executive Director - CHUM McGILL UNIVERSITY	Date: 0100(
By : Name : Sandra Crocker Title : Assistant Vice-Principal (Research and International Relations)	Date :
By: Name: D. Joe Irvine Title: Director, TTBE	Date :
CREE BOARD OF HEALTH AND SOCIAL SERVICES OF JAMES BAY	
By: Name: Mabel Herodier Title: Executive Director	Date:
CREE NATION OF MISTISSINI	
By:	Date:
WHAPMAGOOSTUI FIRST NATION	
By:	Date:

Affaires juridiques Legal Affairs

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CENTRE DE RECHERCHE DU CHUM

L'UNIVERSITÉ DE MONTRÉAL	
By: Jacques Turgeon, B.Pharm., Ph.D. Director of Research - CHUM	Date:
CENTRE HOSPITALIER DE L'UNIVERSITÉ DE MONTRÉAL	
By : Serge LeBlanc Acting Executive Director - CHUM	Date:
MeGILI. UNIVERSITY	
By: Name: Sandra-Crocker Title: Assistant Vice-Principal (Research and International Relations)	Date: Mus 27. 2009
UNIVERSITY OF OTTAWA	
By : Name : D. Joe trvine Title : Director, TTBE	Date :
CREE BOARD OF HEALTH AND SOCIAL SERVICES OF JAMES BAY	
By: Name: Mabel Herodier Title: Executive Director	Date:
CREE NATION OF MISTISSINI	
By: Name: John Longchap Title: Chief	Date:
WHAPMAGOOSTUI FIRST NATION	
By: Name: Losty Mamianskum Title: Chief	Date:

CENTRE HOSPITALIER DE L'UNIVERSITÉ DE MONTRÉAL

Jacques Turgeon, B.Pharm., Ph.D. Director of Research - CHUM CENTRE HOSPITALIER DE L'UNIVERSITÉ DE MONTRÉAL By:	By:	Date :
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By: Date:	Serge LeBlanc	
By: Date:	Acting Executive Director - CHUM	
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CENTRE HOSPITALIER DE L'UNIVERSITÉ DE MONTRÉAL

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Jacques Turgeon, B.Pharm., Ph.D. Director of Research - CHUM	
CENTRE HOSPITALIER DE L'UNIVERSITÉ DE MONTRÉAL	
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McGILL UNIVERSITY	
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UNIVERSITY OF OTTAWA	
Name: D. Joe Irvine Title: Director, TTBE	Date :
CREE BOARD OF HEALTH AND SOCIAL SERVICES OF JAMES BAY	
Name Mabel Herodier Title: Executive Director	Date: Sept. 14 log
CREE NATION OF MISTISSINI	
Name: John Longchap Title: Chief	Date:
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Name: Losty Mamianskum	Date:
Title: Chief	

CENTRE HOSPITALIER DE L'UNIVERSITÉ DE MONTRÉAL

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By :Serge LeBlanc	Date:
Serge LeBlanc Acting Executive Director – CHUM	
McGILL UNIVERSITY	
By: Name: Sandra Crocker Title: Assistant Vice-Principal (Research and International Relations)	Date :
UNIVERSITY OF OTTAWA	
By :	Date :
CREE BOARD OF HEALTH AND SOCIAL SERVICES OF JAMES BAY	
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By: Name: John Longchap Title: Chief	Date: Sept 8, 2009
WHAPMAGOOSTUI FIRST NATION	
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