

GUIDELINES FOR UNIVERSITY SPIN-OFFS

1. Purpose and Scope

McGill University has a mission to carry out research and scholarly activities according to the highest standards of international excellence. As part of this mission, McGill supports the knowledge mobilization and transfer of discoveries and inventions made by its researchers, professional staff and trainees working in its research facilities. One form of such knowledge mobilization is the commercial development of intellectual property. McGill understands that commercialization of such assets may include, at some stage, the creation of spin-off companies that will assume the commercial activities linked to the assets. However, the creation and implementation of the spin-off to develop a commercially valuable McGill technology must be timed carefully to bring the technology to market when it is sufficiently mature. In many instances, staying in research and development mode in the laboratory of the principal investigator (PI) may prove more advantageous than immediately pursuing the spin-off route. The “in-house” R and D approach can also build value in a non-dilutive fashion without the need to incur additional expenses for rent, management and other operating costs, while maximizing the use of key resources, sophisticated equipment, supporting infrastructure and expert personnel such as graduate, and post-graduate trainees and other professionals. Furthermore, R and D activities conducted in the University setting can be supported by grants and other programs from federal, provincial, and local agencies and by innovation grants available at McGill. Hence, McGill encourages researchers to consider carefully the “pros” and “cons” of when to start a spin-off to develop a commercially valuable asset discovered at McGill.

Although McGill favors creating and operating such spin-off companies outside of the University premises, it recognizes that in the absence of a formal dedicated space to that effect at McGill (e.g., an incubator facility), such spin-off companies may wish to operate on University premises for a certain period of time. Such an approach may facilitate the early phase of commercialization by taking advantage of existing infrastructure and expertise that gave rise to the initial discovery/invention, thereby increasing chances of success, including financing for the independent operation of the spin-off outside McGill premises. However, while supporting these important goals, it is also understood that this early phase of “intra-mural” operation of a spin-off should only be for the early stage of commercialization, should be time-limited, and should be conducted in a way that does not impede the academic mission of the laboratory. Importantly, such activities must not create unmanaged or undeclared conflicts of interest or conflicts of commitment (as per the *Regulation on Conflict of Interest*), and should protect the independence of the academic mission of the University. This includes all aspects of the training of graduate students and post-doctoral fellows who may work in the immediate laboratory environment of the spin-off. Hence, there is a need for formal and well-defined guidelines and a regulatory framework for such commercialization activities. In general, the research mission of the University, its employees and its students, and the interests of companies must be kept separate. While the goal of the principal investigator (PI) and any affiliated personnel or collaborators is to carry out research and development in a specific field, the spin-off company’s goal is to develop research results to the stage of commercialization (e.g. creation of a marketable product). This distinction is an over-arching guiding principle for the presence of a spin-off in the confines of a McGill PI’s research laboratory.

2. McGill Spin-off Designation

To address some of the above-mentioned issues, the concept of the “McGill Spin-off” (MSO) is proposed as a designation that would be acquired by companies (start-up commercial enterprises with a for-profit vocation) that are created by McGill researchers, postdoctoral fellows, or graduate trainees, are based on McGill-developed intellectual property, and wish to operate on McGill premises for a period of time. Obtaining such a designation will require the spin-off, its founder(s) and its employees to fulfill certain obligations that would provide an operational framework; one that includes University oversight to preserve the academic mission of the University while avoiding conflicts of interest. On the other hand, the MSO designation would grant certain benefits to the company, including access to physical infrastructure, equipment, and other resources and advantages at McGill, and linkage to the laboratory where the discovery was made. For clarity, these Guidelines for University Spin-Offs do not apply to spin-offs that qualify as an MSO based solely on their participation in the Mitacs e-Accelerate program. It is recommended to consult the specific regulations regarding Mitacs e-Accelerate or other entrepreneurship opportunities before participating in those programs.

Below is a proposed description of the requirements and arrangements for an MSO:

- 2.1 The MSO must be based on discoveries, inventions, technologies, intellectual property or other tangible assets developed during research activities at McGill conducted by a McGill researcher, or by a postdoctoral fellow, or graduate trainee who have a link with McGill either as an employee or a student.
- 2.2 Such intellectual property, inventions or technologies must have been duly disclosed to the Office of Innovation and Partnerships, and have an active report of invention (ROI).
- 2.3 If rights to the invention or technology have been transferred back to an individual PI and their collaborators (transfer of rights per section 6.3 in the *Policy on Inventions and Software*), development of this technology under the MSO designation will not be allowed, and the spin-off will not be permitted to operate at McGill. Investigators who would have acquired rights to the invention and technology (transfer of rights) leading to a spin-off already established in their lab will be granted a six (6) month grace period to move the spin-off outside the University. Should a PI who has chosen the transfer of rights option wish to retain a previously established spin-off in their laboratory (and obtain the MSO designation), they can enter into discussions with the Office of Innovation and Partnerships to negotiate a licensing agreement and obtain the MSO designation, pursuant to the required approval process as described below.
- 2.4 An MSO cannot operate without explicit permission of the University, and is contingent upon approval by the Dean of the Faculty or delegate.
- 2.5 The MSO should be a duly incorporated commercial entity and should have or be seeking independent financing at the time of application for the MSO status.
- 2.6 The MSO will have to have a formal licensing agreement in place with McGill to govern the development and commercialization of the technology, invention or discovery, including licensing fees, and/or distribution of proceeds, and/or equity position of McGill in the MSO (obtained through negotiations with the Office of Innovation and Partnerships).

- 2.7 An application to obtain the MSO designation will be filed with the Office of Innovation and Partnerships at McGill, for formal approval by the Vice-Principal (Research and Innovation) (VPRI), and the Dean of the Faculty. In collaboration with the Department Chair, and the Dean of the Faculty, (or delegate), the VPRI will provide oversight for the operation of the MSO on University premises, including reporting, conflict of interest documentation and approval, and agreements for utilization of space and equipment and other university resources (see below). The Faculty may consult with Facilities Management to ascertain that arrangements with the MSO are compatible with current infrastructure. However, the University may not be in position, and is under no obligation, to provide facilities for the MSO and will have the final say in such matters. The use of space by the MSO should not be the basis for requests by the PI for additional space at McGill, unless such a request is specifically approved by the Department, and the Dean of the Faculty.
- 2.8 The MSO status will allow the company to operate on McGill premises on a temporary basis and subject to formal agreement. The operation of the MSO on McGill premises, if approved by the Dean of the Faculty or delegate, and subsequent to review of space and resources, will normally be limited to a maximum period of two (2) years following granting of the MSO status, unless special arrangements are made through a recommendation of the Chair of the Department, and approval by the Dean of the Faculty, and the VPRI.
- 2.9 The MSO will have access to basic McGill infrastructure otherwise available to McGill employees such as internet, mail, and utilities as well as the advice of staff in the Office of Innovation and Partnerships. However, such companies are expected to have their own management personnel and legal counsel.
- 2.10 The MSO will obtain permission to use space, specialized equipment, and unique reagents on a fee-for-service basis and negotiated on a case-by-case basis by a representative of the MSO and the Chair of the Department (or equivalent), and a representative of the Dean of the Faculty. This agreement will also need approval by the offices of the Dean and the VPRI. A template for this agreement will be developed by the Office of Innovation and Partnerships. This agreement may also be part of a research contract or a sponsored research agreement between McGill and the MSO (see below).
- 2.11 Any research collaboration between the MSO and the University laboratory will be done under formal research agreements (sponsored research agreement, research contract, service agreement, licensing, etc.), including for third party funding or financing where the company and the McGill laboratory act as partners in specific research programs. These agreements will be duly executed by the Office of Innovation and Partnerships at McGill.
- 2.12 The MSO will keep clear records that establish and document its developmental research activities (including employee information) and will file an activity report with the Office of Innovation and Partnerships every six (6) months during its operation on McGill premises.

- 2.13 An oversight committee chaired by the VPRI or delegate will be established to confidentially review the research activities of the MSO and the University laboratory to make sure their activities remain separate and distinct. The committee will also verify that activities and materials associated with such activities comply with University safety standards. In addition to the chair, one committee member will be appointed by the MSO and one will be identified jointly. The jointly identified member should be a specialist in the field who has no tie to the MSO or the research laboratory and who can act in an objective and impartial manner.
- 2.14 The MSO will be granted a preferential overhead rate of ten percent (10%) on research contracts and sponsored research agreements for collaborative work conducted during their term on McGill premises.
- 2.15 McGill personnel, excluding the PI but including McGill students, McGill post-doctoral fellows, or McGill research assistants or research associates, either from the McGill PI's laboratory or from the same unit, cannot serve as MSO employees at the same time as their McGill appointment. The above personnel will only be allowed to work for the MSO once they have completed their studies or ceased their employment at McGill. McGill personnel can participate in research projects from MSOs, where the terms for such projects are negotiated with I+P and include the necessary provisions for conflict of interest, publication, intellectual property, project costs, etc., as part of sponsored research agreements or contracts.
- 2.16 The MSO may not employ a McGill PI for a period greater than one (1) day per week, as per the University guidelines for consulting (maximum forty-eight (48) days per year). Any commitment beyond this requires explicit agreement with the Dean of the Faculty and a commensurate reduction in University salary. The McGill PI must also avoid a conflict of time commitment, recognizing that his/her primary commitment of employment is towards the academic mission of the University.
- 2.17 Except for the McGill PI, the MSO must operate with its own employees only, and the MSO must provide proof of liability insurance prior to being granted access to McGill premises. The MSO employees will act in accordance with the University rules and regulations governing proper behaviour in the work place. The behaviour of employees is the responsibility of the MSO employer and any infringement of University standards of behaviour will be subject to dismissal or exclusion of the MSO from McGill premises with no compensation from the University.
- 2.18 The PI linked to, or hosting, the MSO in his/her laboratory will file a duly completed conflict of interest (COI) statement and management plan at least once per year, disclosing financial details and other aspects of the relationship of the PI with the MSO. Likewise, all students, post-doctoral fellows, and laboratory members must be informed in writing of the operation of the MSO in their environment, including possible COI linked to its operation. Updated COIs and management plans must be filed whenever there is a substantial change in circumstances.

3. Modifications to Guidelines

The Guidelines may be modified from time to time by the Vice-Principal (Research and Innovation) after appropriate consultation with the Senior Administration, Deans, the Technology Transfer Office, and members of the University community and affiliated institutions having experience and expertise in matters of inventions, software, spin-offs and commercial development of such, as per the *Policy on Inventions and Software*.

Initial Approval Date:	September 29, 2020
Last Modified Date:	January 20, 2021
Executive Sponsor:	Vice-Principal (Research and Innovation)
Reference Documents:	Policy on Inventions and Software