

FACULTY OF MEDICINE

Guidelines for Faculty of Medicine Graduate Students and Supervisors in the Context of Commercialization of Inventions Based on Thesis-Related Research

The following guidelines are meant to deal with graduate student training in the context of the commercialization of inventions based on thesis-related research. They apply in the following circumstances: i) thesis-related research funded through an industry contract, where research agreements are in place from the outset; ii) thesis research funded by non-industry sources where the opportunity and desire to commercialize the results are either anticipated or arises during the course of the research; and, iii) ongoing thesis research where the opportunity and desire arise to enter into a research agreement with industry¹.

The guidelines described here are supplementary to University policies and nothing in these guidelines shall be interpreted as superseding the terms and conditions of these policies.

These guidelines received the unanimous approval of the Vice Presidents Research at the fully affiliated teaching hospitals on May 3, 2004 at a meeting of the Hospital University Research Co-ordinating Committee. The Faculty of Medicine Dean's Executive approved this document on May 12, 2004.

SUMMARY OF GUIDELINES

Graduate Student Status at the University of Toronto

- Doctoral stream graduate students at the University of Toronto are supervised by graduate faculty members who, along with their Departments and Faculties, are responsible for providing an annual stipend up to the first 5 years in their program of study. In the Faculty of Medicine, the entire stipend is received as supplemental (T4A) income since Teaching Assistant salary payments are not considered part of the guaranteed graduate student stipend. Hence, the relationship between the graduate student and supervisor is not an employment arrangement. The source of graduate student stipends may include the supervisors' research grants and in some cases industry contracts. To avoid conflict of interest, it is strongly recommended that supervisors not employ their graduate students whether the work is thesis-related or not.

Rights and Ownership of Inventions

Being an inventor (or being one of several inventors) does not necessarily mean the rights and ownership of the invention rest with that individual (or individuals). Instead, these rights and ownership are assigned through legal contracts and policies. The following should be noted:

¹ All thesis research using either human subjects or animals must undergo an ethical review before the research may be undertaken. The relevant institutional research ethics committee is permitted to review legal agreements.

- The rights and ownership of inventions are stipulated in industry contract agreements.
- In the absence of an industry contract agreement or any other legally recognized agreement, the rights and ownership of inventions are governed by the Inventions Policy of the University. Exceptions are for those graduate students who are supervised off-campus, who conduct their thesis -related research in a fully affiliated teaching hospital or its research institute, and who do not make substantial use of University facilities. In that case, the rights and ownership of inventions are governed by the affiliated hospital/research institute policies, unless other arrangements have been made and agreed to by the parties involved.

Disclosure by the Supervisor

- It is the joint responsibility of the supervisor and Graduate Department in collaboration with the affiliated hospital/research institute to ensure every prospective or continuing graduate student is provided with complete and up-to-date information about the rights and ownership of inventions.
- In cases where research agreements are already in place, supervisors must inform graduate students in writing of any terms and conditions in the agreement that will affect (or could be seen to affect by a reasonable observer) their research with respect to who has rights and ownership of the invention. In cases where the commercialization of inventions resulting from thesis-related research is anticipated, or arises during the course of the research, supervisors must inform their existing or potential graduate students of this possibility. In cases where the potential for the commercialization of inventions based on thesis-related research results arises during the course of the research, the supervisor and student shall endeavour to come to a mutually acceptable understanding, to be detailed in writing, with regard to entering any agreement that assigns rights and ownership of an invention. (see details of process in the full text below)

Communication and Publication

- The University of Toronto and its fully affiliated teaching hospitals and research institutes are dedicated to the dissemination of knowledge and do not enter into agreements that prohibit publication of research results. While the results of the research cannot remain confidential, it is permitted to have limited delays in publication and communication of research results to ensure legal protection of the invention by the interested parties and/or to secure an agreement with industry. These permitted delays shall be in keeping with commonly accepted scholarly standards and existing policies of the School of Graduate Studies.

Facilitation of Agreement Pertaining to Issues Arising from the Commercialization of Inventions Based on Thesis-Related Research

- If a disagreement between the supervisor and student arises related to the commercialization of inventions based on thesis-related research that they cannot resolve themselves, the first step is to seek the advice and facilitation of an agreement from the thesis program advisory committee. The next step, if there is no agreement, is to work with the Graduate Coordinator and Departmental Chair, and in the case of research conducted in an affiliated hospital/research institute the Vice President Research should work collaboratively with the Departmental

Chair. Failing resolution, the student (with the support of the Graduate Department) should seek the help of the Associate Dean Division IV at SGS. Prompt attention to disagreements and documentation of the resolution process at each level are strongly advised.

Definitions

For the purpose of these guidelines, the following definitions are used:

1) **"Inventions"** shall be within the meaning of the University of Toronto's Governing Council Inventions Policy (June 2, 2002). [An exception is where the graduate student is supervised off-campus, conducts his or her thesis-related research in a fully affiliated teaching hospital (or its research institute), and does not use substantial University facilities. For these exception cases, the off-campus institutions definition of "inventions" shall be used.]

The University of Toronto defines inventions as:

- a) "new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter" [Patent Act, R.S.C. 1985, c.P-4, s.2] whether or not patentable;
 - b) computer software pursuant to section 2.6 of the University's Copyright Policy;
 - c) research data or research tool, including, without limitation, biological material and other tangible research material; and,
 - d) proprietary information, know how or trademark related to any of the foregoing items;
and includes all legal and equitable rights relating to such property. This Policy does not apply to inventions created in the course of demonstrable private research unrelated to the Inventor's University functions or in the course of private consulting activities to outside bodies, when such activities do not involve any substantial use of University facilities.
- 2) **"Rights and ownership of inventions"** refers to the ability to assume responsibility for legally protecting and marketing the invention, finding a licensee, negotiating a licence agreement and administering that agreement. Assignment of rights and ownership takes place under specific stipulations as to how (if at all) the net revenues are to be shared and for the purposes here, those stipulations are assumed to be included with the rights and ownership of inventions.
- 3) **"Inventor"** is that person (or persons) who was responsible for the creative breakthrough and who would be recognized as the inventor in patent law. Determining inventorship is not the same as determining authorship of scientific papers.
- 4) **"Thesis-related research"** shall mean research conducted in partial fulfillment of a MSc or PhD degree in a Graduate Program in the Faculty of Medicine at the University of Toronto.

PREAMBLE

Two main factors have led to the need to examine the current practices and policies with regard to graduate student training in the context of the commercialization of research results. The first stems from an increase in research funding from industrial sources. Typically, industry-funded research agreements provide the industrial partner with considerations regarding the ownership and/or licensing of the ensuing results or intellectual property. As such, usually these agreements also include terms pertaining to confidentiality and the dissemination of results, and issues that must be addressed in the context of graduate student education.

The second is simply a reflection of the fact that the potential for the commercialization of research results from the biological/medical sciences has risen dramatically. The university and hospital research institutes are actively engaged in technology transfer and provide scientists and graduate students alike with services related to research partnering, technology transfer and commercialization.

The increased opportunities for the commercialization of biological/medical research have also led to an increase in the number of scientists who either own or consult for companies. If these companies in turn support research involving the training of graduate students under the supervision of these scientists, there exists a clear potential for conflict of interest. These guidelines are provided to ensure that in such situations, graduate student education and supervision follow a course based solely on academic considerations.

At the outset it should also be stated that the standards for research performed by graduate students in partial fulfillment of the requirements of a MSc or PhD degree, in the Faculty of Medicine, do not change in relation to the potential for commercialization of inventions. Regardless of the source of funding, location of the research or the outcome of the research, the fundamental requirements of originality, contribution to new knowledge and desirability of peer-reviewed publication remain the cornerstone of the advanced degrees conferred by the University of Toronto.

In addition to the specific policies that govern the sharing of intellectual property, it should also be recognized that the University, hospitals and their research institutes, scientists and graduate students can enter into contract agreements which assign part or all of their intellectual property to other parties, typically a company, wishing to fund the research in exchange for the right to commercialize the results. These agreements usually include terms pertaining to confidentiality and the delay of publication of research results.

However, the academic needs of the student enrolled in a Graduate Department at the University of Toronto are a priority. The freedom of graduate students to communicate their research findings with minimal or no delay, either orally or in print, must be guaranteed. The Faculty of Medicine recognizes its responsibility to inform and guide its graduate students and their supervisors to ensure that the academic freedom, the integrity of the research and rights of its graduate students in an industry-supported environment are protected. Therefore, it is imperative that graduate students are fully informed by their existing or potential graduate supervisors when contractual agreements between an industry sponsor and the University, affiliated hospital or research institute, exist or are contemplated.

The following are Faculty of Medicine guidelines for graduate students engaged in thesis-related research in an industry-supported environment and links to supportive documents.

1. GRADUATE STUDENT STATUS AT THE UNIVERSITY OF TORONTO

Graduate students who are engaged in full time thesis research in a doctoral degree program, which also includes MSc and PhD students in the Faculty of Medicine, are guaranteed a minimum of \$12,000 plus tuition as an annual stipend for up to 5 years of their program. See the following web site for complete details:

<http://www.utoronto.ca/provost/gradfinanc/FinalMay2000/finalMay.htm>.

In the Faculty of Medicine, the Graduate Chairs have agreed that all graduate programs in Medicine should aim to provide a minimum annual stipend at the level of the CIHR doctoral studentship. The graduate student stipend is considered supplemental (T4A) income. Graduate students are not employed in this arrangement either at the University or the affiliated hospitals/ research institutes. The graduate student stipend funding is often derived from multiple sources including student awards, University of Toronto fellowship funds and the supervisor's research grants. Students may receive a stipend from an industry contract provided the conditions described below are fulfilled.

The Graduate Departments in the Faculty of Medicine and the affiliated hospitals/research institutes are urged to discourage employment of graduate students by their supervisors for the purpose of engaging in research whether or not this work is relevant to their thesis project or to an industry contract. The rationale is that the relationship between supervisor and student may lead to a conflict of interest if the supervisor is also the employer of the student. The Faculty is aware that many students must work part time to support themselves, and students employed by faculty members who are not their thesis supervisors is an acceptable arrangement that avoids potential conflict of interest related to the student-supervisor relationship.

2. RIGHTS AND OWNERSHIP OF INVENTIONS

Being an inventor (or being one of several inventors) does not necessarily mean the rights and ownership of the invention rests with that individual (or individuals). Instead, these rights and ownership are assigned through legal contracts and policies. Students whose contribution would be recognized in patent law as an “inventor”, should be named as an (joint) inventor in any patent application. If the individual is employed (receiving T4 income) to do the work that constitutes their contribution to the invention, the individual may be required to assign any patent rights in the application to their employer. The following should be noted:

- The rights and ownership of inventions are stipulated in industry contract agreements.
- In the absence of an industry contract agreement or any other legally recognized agreement, the rights and ownership of inventions are governed by the Inventions Policy of the University. (<http://www.library.utoronto.ca.rir.invent/html>). An exception are for those graduate students who are supervised off-campus, who conduct their thesis-related research in a fully affiliated teaching hospital or its research institute, and who do make substantial use of University facilities. In that case, the rights and ownership of inventions are governed by the affiliated hospital/research institute policies, unless other arrangements have been made and agreed to by the parties involved.

3. DISCLOSURE BY THE SUPERVISOR

Similar to graduate students engaged in thesis-related research in the absence of industry sponsorship, graduate students in an industry-supported environment will be allowed to develop their research projects in accordance with normal academic criteria. In particular, their research program should not be changed simply for non-academic reasons.

It is the joint responsibility of the supervisor and Graduate Department in collaboration with the affiliated hospital/research institute to ensure every prospective or continuing graduate student is provided with complete and up-to-date information about the rights and ownership of inventions. Faculty members who are also graduate supervisors, whose research is, or is intended to be supported by a commercial or industry sponsor are required to disclose to their existing or potential graduate students the nature of this involvement as it pertains to thesis-related research. Students must be fully informed in writing by their supervisors or potential supervisors about thesis research projects that are restricted by conditions of agreements between the University or affiliated hospital/research institute and the sponsor that will affect them in any manner. It is expected that a contract agreement will not limit the ability of the graduate student to disclose their original research findings in the form of public presentation and publication beyond a reasonable timeframe (see below Communication and Publication) necessary for filing a patent. Graduate Departments are responsible for ensuring that supervisors and students have access to consultation with experts about industry-sponsored research, commercialization and the assignment of rights and ownership of an invention.

Once graduate students are fully informed about the potential limitations of industry sponsorship, they have the right to choose whether they will engage in thesis-related research that is either funded by industry, or aimed at the commercialization of inventions based on thesis-related work.

It is incumbent on the student, supervisor and Departmental Chair to ensure that the student is fully aware of the consequences of agreement to engage in such research.

In cases where research agreements are already in place, supervisors must inform graduate students in writing of any terms and conditions in the agreement that will affect (or could be seen to affect by a reasonable observer) their research with respect to who has rights and ownership of the invention. In cases where the commercialization of inventions resulting from thesis-related research is anticipated, or arises during the course of the research, supervisors must inform their existing or potential graduate students of this possibility. In cases where the potential for the commercialization of inventions based on thesis-related research results arises during the course of the research, the supervisor and student shall endeavour to come to a mutually acceptable understanding, to be detailed in writing, with regard to entering any agreement that assigns rights and ownership of an invention. It is unreasonable to expect that a student abandon a research project that has progressed significantly if mutually agreeable terms cannot be found.

It is strongly recommended that agreement by the student to engage in an industry-sponsored thesis-related research project be indicated in writing to the supervisor with a copy to the Chair of the Graduate Department, and in the case of research conducted at an affiliated hospital/research institute a copy should be forwarded to the Vice President Research. This agreement on the part of the student may, in some instances, also require them to sign the contract. Continued annual disclosure by the student and supervisor to the Departmental Chair and the Vice President Research is strongly recommended for the duration of the involvement of the graduate student in an industry-supported project.

4. COMMUNICATION AND PUBLICATION

Ai General University Policy for Publications

The Publication Policy for the University of Toronto, which applies to all members of the university community including faculty and students, states, "results of research undertaken at the University shall be fully publishable..." The Policy, however, does recognize the rights of an industry or commercial sponsor and accepts a reasonable delay (60 to 90 days) in the submission of research findings for publication. Similar considerations should be granted to professors and students who seek to take the steps required to protect their intellectual property.

Aii Publications Arising From Thesis-related Research

To avoid unreasonable delays in the completion of their doctoral programs, graduate students who are engaged in thesis-related research in an industry supported environment should be free to communicate their research findings with no or minimal delay. Submissions by graduate students for publication, including abstracts at scientific meetings, of their thesis-related research may be delayed no longer than 90 days from the time the manuscript is submitted to the sponsor for review. This delay should be sufficient for the filing of a patent application if the research is deemed to have commercial potential, and allows the industry sponsor an opportunity to request deletion of any proprietary information that has been specifically defined previously in the non-disclosure agreement.

Aiii Publication of the Thesis

Under University policy, the thesis is the copyrighted work of the author. As such, publication of the thesis including placement in the library cannot be delayed without consent of the author. In the case of a thesis containing research conducted under industry sponsorship, it is reasonable to submit the thesis for review by the sponsor for a period of up to 90 days. This delay should be sufficient for the filing of a patent application if the research is deemed to have commercial potential, and allows the industry sponsor an opportunity to request deletion of any proprietary information that has been specifically defined previously in a the non-disclosure agreement. Graduate students hold the copyright to the final thesis. The publication of the thesis is governed by the current policies of the School of Graduate Studies.

B. Oral Communications

Graduate students must be free to present and discuss their research in the usual University forums such as departmental seminars, scientific days, meetings of the student's thesis advisory committee for progress assessment, and thesis examinations by the Graduate Department and School of Graduate Studies. Normally, thesis-related research findings are not considered confidential and, therefore, subject to examination at the thesis defence. The exception includes the data or information provided by the sponsor in which case a confidentiality agreement regarding the data or information may have to be arranged between the sponsor and the University to facilitate the thesis examination conducted according to existing Departmental and School of Graduate Studies standards and procedures. In addition, there may be a time delay on oral communication if the student or research project is funded by a contractual agreement

between the sponsor and the University or affiliated hospital/research institute. Generally, research results for oral presentation should be treated similarly to publications or abstracts that are submitted to the sponsor for review for up to 90 days, following which the student should be allowed to present their research findings in a public forum. Again, considerations should be granted to professors and students who seek to take steps required to protect their intellectual property.

5. INTELLECTUAL PROPERTY ASSOCIATED WITH INVENTIONS

General Intellectual Property

In the absence of legal obligations in the form of an industry research agreement, neither the student nor the supervisor has exclusive intellectual property rights. Intellectual property may be developed as a result of interaction of the student either solely with the supervisor, or with the supervisor and a research team. While the student holds copyright of the thesis as a written document, any data or inventions are not the exclusive property of either the student or the supervisor. For a more detailed discussion see the document "Intellectual Property Guidelines for Graduate Students and Supervisors at the University of Toronto" at <http://www.sgs.utoronto.ca/oldlinks/intellectualpropertyguidelines.asp>.

Intellectual Property Associated with Inventions

In the case of research conducted in an industry-supported environment, ownership of intellectual property associated with inventions is firstly governed by the terms of the research contract between the sponsor and the University or the affiliated hospital/research institute.

In the absence of such a research agreement, graduate students are governed by the University of Toronto's Governing Council Inventions Policy (June 2, 2002). This policy provides that generally the University and the inventor share rights to an invention and the given inventor(s) has the option of taking personal ownership under certain terms and conditions.

For graduate students who are supervised off-campus, who conduct their thesis-related research in an affiliated hospital or research institute, and who do not use substantial University facilities, the rights and ownership of inventions are governed by the affiliated hospital /research institute policies, unless other arrangements have been made and agreed to by the parties involved.

6. FACILITATION OF AGREEMENT PERTAINING TO ISSUES ARISING FROM THE COMMERCIALIZATION OF INVENTIONS BASED ON THESIS-RELATED RESEARCH

The Faculty of Medicine expects that the relationship between graduate students and their supervisors will exemplify mutual respect. As such, supervisors must be sensitive to the potential for the inappropriate use of their position of authority with their students. Care must be taken to ensure that the relationship between the supervisor and her/his graduate students reflects a high degree of integrity with respect to the management of authority. If a disagreement between the supervisor and student arises related to the commercialization of inventions based on thesis-related research which they cannot resolve themselves, the first step is to seek the advice and facilitation of an agreement

from the thesis program advisory committee. The next step, if there is no agreement, is to work with the Graduate Coordinator and Departmental Chair, and the Vice President Research in the case of research conducted at an affiliated hospital/research institute. Failing resolution, the student (with the support of the Graduate Department) should seek the help of the Associate Dean Division IV at SGS. Prompt attention to the disagreement and documentation of the resolution process at each level are strongly advised. Supervisors and graduate students should also refer to the Faculty of Medicine's "*Principles and Responsibilities Regarding Conduct of Research*" and "*Guidelines to Address Research Misconduct*" found at <http://www.library.utoronto.ca/medicine.medUT/ethics.html>.