POLICY ON THE ETHICAL CONDUCT OF RESEARCH INVOLVING HUMANS

PRESENTED TO THE RESEARCH COMMISSION ON DECEMBER 7, 2011

PRESENTED TO THE ASSEMBLÉE DE DIRECTION ON JANUARY 17, 2012

PRESENTED TO THE CONSEIL ACADÉMIQUE ON JANUARY 23, 2012

PRESENTED TO THE BOARD OF DIRECTORS ON FEBRUARY 2, 2012

PRESENTED TO THE CONSEIL ACADÉMIQUE ON JANUARY 23, 2013

PRESENTED TO THE BOARD OF DIRECTORS ON FEBRUARY 11, 2013

RESEARCH AND INNOVATION DIRECTORATE
POLYTECHNIQUE MONTRÉAL

1. PREAMBLE

Polytechnique Montréal is a major player in Canadian research in several engineering disciplines. As at most universities around the world, some research projects carried out by Polytechnique professors, employees and students, which are aimed at solving problems, developing new technologies and understanding as yet unexplained phenomena, might require the participation of human subjects. This is the case, for instance, when researchers administer questionnaires or conduct surveys or interviews, carry out experiments, collect confidential data on individuals, make secondary use of collected data for purposes other than the proposed research, and conduct research using cadavers, human remains, tissues, biological liquids, and so forth.

Research is a step into the unknown. Because it seeks to understand something not yet revealed, research often entails risks to participants and others. These risks can be trivial or profound, physical or psychological, individual or social. It is therefore important to develop projects in such a way as to meet strict ethical and scientific criteria designed to protect human participants.

2. SCOPE

Conducting research involving human subjects is a privilege based on the confidence and trust shown by society in general and research participants in particular toward the institution and its researchers. To maintain this trust, on which certain research projects depend, researchers must respect an ethics framework and adhere to its moral, legal and ethical imperatives. The application of the principles, standards and articles presented in this Policy reflects Polytechnique Montréal's desire to i) ensure respect for the dignity of all participants; ii) provide participants with the best possible protection in the context of research activities carried out by researchers; and iii) meet Québec, Canadian and international standards, as well as the expectations of funding agencies and the university's governing bodies, in order to maintain and promote its reputation and credibility both within the academic community and among external partners.

This Policy sets out the measures to be taken in research requiring the participation of human subjects through tests, stimuli or questions aimed at answering a research question, including the use of subjects' data or biological materials, or data or biological materials to be held in biobanks for subsequent use, taking in account the risks these activities involve.

This Policy applies to all research conducted or supervised at or outside Polytechnique Montréal by professors, staff or students, or by external individuals using Polytechnique resources, whenever said research involves the participation of humans as research subjects, or parts, products, tissues, cells, genetic material or data from humans.

Research involving any of the following elements must be reviewed and approved by Polytechnique's Research Ethics Board (REB) before the research begins[1]:

- the gathering of personal information through surveys, questionnaires, interviews, observations, etc. allowing for the direct or indirect identification of individuals;
- the taking of photographs or the production of images or prints that could identify individuals;
- the consultation of personal, medical, administrative or other records;
- tests or other procedures requiring the participation of human subjects;
- cadavers or human remains;
- human biological materials (tissues, organs, blood, plasma, serum, DNA, RNA, proteins, cells, skin, hair, nail clippings, urine, saliva and other body liquids);
- biological materials related to human reproduction (fetuses, fetal tissues, human reproductive materials).

These examples are not exhaustive. In case of doubt, researchers are invited to contact the REB secretary or Chair for advice.

It is important to note that REB reviews are only carried out for research projects, not research programs.

3. EXEMPTIONS

Research projects that do not require REB review include:

- Projects based on information that is i) available to the public; ii) legally accessible to the public and appropriately protected by law; and iii) publicly accessible and with no reasonable expectation of privacy[2];
- Certain research projects requiring the gathering of data on organizations, policies, procedures, professional practices or statistical reports from personnel authorized to release information or data in the ordinary course of their employment[3];
- Certain research projects involving the observation of people in public places;
- Research that relies exclusively on secondary use of anonymous information, or anonymous human biological materials, so long as the process of data linkage or recording or dissemination of results does not generate identifiable information;
- All activities that do not constitute research, even though they might use methods and techniques similar to those used in research (e.g., quality assurance and quality improvement studies, program evaluation activities, and performance reviews, or testing within normal educational requirements when used exclusively for assessment, management or improvement purposes).

[1] In other words, before researchers recruit participants, access data, collect human biological materials or use human biological materials held in a biobank.
[2] However, the data linkage of different sources of publicly available information requires REB review.
[3] However, research projects in which individuals are asked for their personal opinions about organizations, or who are observed in their work setting for the purposes of research, require REB review.

For further details on the types of research that do not require REB review, it is recommended to read Chapter 2 of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS2). In all cases, the REB shall decide whether or not a research project shall be exempt from REB review.

4. POLICY FRAMEWORK

This Policy follows the publication, in 2010, by Canada's three federal research granting agencies (NSERC, SSHRC and CIHR), of a second edition of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*[4] which states their position and shared expectations. The new version, commonly referred to as the TCPS2, is the framework on which this Policy is based. Since Polytechnique Montréal has adopted the TCPS2, it has borrowed from it a number of definitions and concepts, and has adapted certain passages without making explicit reference to the *Tri-Council Policy Statement* so as not to make the text cumbersome.

Polytechnique Montréal also applies the measures put forth by Québec's Ministère de la Santé et de Services sociaux in the document *Plan d'action ministériel en éthique de la recherche et en intégrité scientifique*[5], as well as the principles, rules and measures of US organizations, including those of the Department of Health and Human Services, set out in the document *Federal Policy for the Protection of Human Subjects* (45 CFR 46), for research funded by US organizations, along with all other international ethical requirements, according to specific research contexts.

The application of these ethical research rules does not exempt researchers from complying with existing laws in Québec and Canada, and with the rules of professional conduct of relevant professional associations or corporations, if applicable.

In addition, the following policies may apply:

- Probity Policy;
- Policy on Integrity and Conflicts of Interest in Research;
- Policy on the administration of research funds.

The policies and regulations of federal funding agencies (NSERC, SSHRC, CIHR, CFI, etc.) and their provincial equivalents (FQRNT, FQRSC, FRSQ, etc.) may also apply.

5. OBJECTIVES

This Policy sets out ethical principles for the development, conduct, promotion and evaluation of research involving humans. It also describes the scope of its application, the review process based on ethical principles, Polytechnique Montréal's expectations regarding the ethical conduct of research involving humans, and related responsibilities.

6. DEFINITIONS

[4] The official electronic version of this document may be read at http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default

[5] http://ethique.msss.gouv.qc.ca/site/download.php?c6d3e3200feeca4c50623083af406127

The term "**research**" refers to a procedure aimed at advancing knowledge through a structured study or systematic investigation.

For the purposes of this Policy, "**minimal-risk**" research is defined as research in which the probability and magnitude of possible harms incurred by participation in the research is no greater than those encountered by participants in those aspects of their everyday life that relate to the research.

The term "**researcher"** refers to any individual who generally or occasionally carries out research, creation, development or training activities, including professors employed at Polytechnique, lecturers, visiting professors, associate professors, visiting scholars, salaried staff, postdoctoral fellows and students.

The term "**institution**" refers to Polytechnique Montréal.

7. PHILOSOPHY AND GUIDELINES

Polytechnique Montréal adheres to the core ethical principles stated below. These principles mainly serve to guide researchers in their research activities and the institution's REB in its work. The principles are based on a central principle in the ethical conduct of research involving human subjects, namely respect for human dignity. Respect for human dignity requires that research involving humans be conducted in a manner that is sensitive to the inherent worth of all human beings and to the respect and consideration that they are due.

The guidelines in this Policy are based on the following three core principles:

7.1 Respect for persons

Respect for persons recognizes the intrinsic value of human beings and the respect and consideration that they are due. It encompasses the treatment of persons involved in research directly as participants and those who are participants because of their data or human biological materials.

Respect for persons incorporates the dual moral obligations to respect autonomy and to protect those with developing, impaired or diminished autonomy. An important mechanism for respecting participants' autonomy in research is the requirement to seek their free, informed and ongoing consent. An informed choice is one that is based on as complete an understanding as is reasonably possible of the purpose of the research, what it entails, and its foreseeable risks and potential benefits. Certain factors may diminish a person's ability to exercise their autonomy, such as inadequate information or understanding for the purposes of deliberation, or a lack of freedom to act due to controlling influences or coercion. Such constraints may include the fear of alienating those in positions of authority (e.g., informal caregivers, health care professionals, researchers and leaders). Some people may be incapable of exercising autonomy because of youth, cognitive impairment, other mental health issues or illness. Involving those who lack capacity to make their own decisions to participate can be valuable, just and even necessary. For those prospective participants, additional measures are needed to protect their interests and to ensure that their wishes are respected.

7.2 Concern for welfare

The welfare of a person is the quality of that person's experience of life in all its aspects. Welfare

consists of the impact on individuals of factors such as their physical, mental and spiritual health, as well as their physical, economic and social circumstances. Determinants of welfare can include housing, employment, security, family life and social participation. Other contributing factors to welfare are privacy and the control of information about the person, as well the treatment of the person's biological materials.

Concern for welfare means that researchers and the REB should aim to protect the welfare of participants by providing them with enough information to be able to adequately assess risks and potential benefits associated with their participation in the research. To do so, researchers and the REB must ensure that participants are not exposed to unnecessary risks. When such risks are unavoidable, they must be minimized.

7.3 Justice

Justice refers to the obligation to treat people fairly and equitably. Fairness entails treating all people with equal respect and concern. Equity requires distributing the benefits and burdens of research participation in such a way that no segment of the population is unduly burdened by the harms of research or denied the benefits of the knowledge generated from it.

Treating people fairly and equitably does not always mean treating people in the same way. Differences in treatment or distribution are justified when failures to take differences into account may result in the creation or reinforcement of inequities. One important difference that must be considered for fairness and equity is vulnerability, particularly among those with diminished capacity for self-determination.

The recruitment process, both of participants who may become directly involved in research and those who participate as the source of information or biological materials to be used in research, is an important component of the fair and equitable conduct of research.

The importance of research and the need to ensure the ethical conduct of research requires both researchers and REB members to navigate a sometimes difficult course between the two main goals of providing the necessary protection to participants and serving the legitimate requirements of research. In all cases, the REB and researchers must take the perspective of the participant into account, in order to properly evaluate the implications of the proposed research.

8. RESPONSIBILITIES

The ethical conduct of research with humans involves many diverse responsibilities that are shared by all stakeholders in the research process.

8.1 Researchers

All researchers at Polytechnique Montréal and all external individuals using the institution's resources for research involving humans, or parts, products, tissues, cells, genetic material or data from humans, are required to develop research projects that respect the principles and regulations set out in this Policy. They are also responsible for submitting their project to the secretary of Polytechnique's REB.

Although the responsibility is shared, researchers bear the main scientific and ethical responsibility in the choice and conduct of their research activities and the activities of those they direct, guide or supervise.

A "joint responsibility" rule applies to projects carried out by undergraduate and graduate students as part of their training programs. Since professors are in charge of directing and supervising these projects, they must ensure that students submit their proposals to the REB for review. Students, in turn, must respect the methodological and ethical framework of the project, and must inform their research supervisor of how the project is progressing and of any problems that might have ethical implications. Students should actively participate in preparing the file to be submitted to the REB and should, if applicable, be able to defend their project before the REB (usually with their research supervisor).

In all projects involving human subjects, Polytechnique Montréal recommends that researchers i) clearly inform participants about the nature of foreseeable risks and the potential benefits of the research; ii) systematically ensure that foreseeable risks to participants are minimized; iii) provide to participants and to the REB any new information that may impact the participants' welfare or their decision to continue participating in the research; and iv) submit regular reports to the REB on the progress of their research.

8.2 Board of Directors

Polytechnique Montréal's Board of Directors is the body that adopts this Policy and any subsequent amendments. It is also the Board of Directors that grants the REB its authority, as stipulated in this Policy and any amended versions thereof, and that appoints and dismisses REB members.

8.3 Research Ethics Board (REB)

The REB has a mandate to review and provide ethics follow-up for all projects that have not received an exemption or exceptional status recognized by the TCPS2 and that are submitted as part of this Policy. The REB has the power to approve, modify, end or reject any proposal or continuation of a research project involving human participants. In its reviews, the REB will examine the ethical implications of the research design, of the methods and tools to be used, and of the processes used to recruit participants and secure their consent. According to the proportionate approach to ethics assessment, the REB will adapt its level of review according to the risks posed by the research project and will examine the projects it receives according to foreseeable risks, potential benefits and ethical implications. Following initial approval, the REB will monitor the project for its duration.

The Board of Directors delegates to the REB the responsibility of developing, applying and updating this Policy. The REB receives all questions regarding this Policy and related rules. The REB must also advise and support Polytechnique researchers in the application of this Policy and with regard to all ethical issues tied to research involving humans. In delegating the above-mentioned authority to the REB, Polytechnique Montréal is committed to respecting its decisions. In particular, Polytechnique cannot reverse a negative REB decision based on ethical grounds without using the appeal mechanism described in Section 12[6].

Polytechnique Montréal's REB can also act as an appeal committee for another institution according to prior agreements. Its decisions must respect this Policy, which means they must also be based on the minimum standards set out in the TCPS2.

8.4 Dean of Research and Innovation

The Dean of Research and Innovation is responsible for this Policy and must ensure that it is circulated and promoted throughout the Polytechnique community. The Dean also ensures that the REB has the necessary financial and administrative support, as well as ongoing training for its members and for the Polytechnique community. In addition, the Dean will appoint a person to support the REB's activities and act as its secretary.

9. COMPOSITION OF THE REB

Polytechnique Montréal's REB consists of at least five members, namely:

- two professors active in research, with an expertise in the methods, fields and disciplines that fall within the jurisdiction of the REB;
- a person who is knowledgeable in ethics;
- a person who is knowledgeable in law (this person cannot be Polytechnique's legal counsel);
- a person from a community that is served by Polytechnique Montréal, but that has no affiliation with the institution[7].

Quorum for an REB meeting shall consist of these five members. If necessary, other members can be added to the REB. However the REB can have no more than ten members. One of the regular members will chair the REB.

Substitute members may also be appointed to replace regular REB members in cases of conflict of interest related to a specific project, or the inability of a member to attend an REB meeting. The administration of the REB is carried out by the REB secretary.

[6] However, Polytechnique Montréal reserves the right to prohibit certain types of research at Polytechnique, regardless of whether the project has received ethics approval from the REB.

[7] One member from the community must sit on the REB for every four regular members. Thus, if there are eight or more members, the REB must include two additional members from the community.

Appointments, including those of the Chair and substitute members, are made by the Board of Directors, on the recommendation of the REB, following consultation with the Research Commission. Terms last three years and are renewable.

When the nature or scope of a project requires an expertise or a competency not available from regular REB members, the Chair may call on external experts. These experts can take part in the REB's discussions, but they do not have voting rights if a vote is required. The REB may also take into account the deliberations and decisions of other Polytechnique committees responsible for assessing certain risks (e.g., the IT Risk Review Committee). Polytechnique senior administrators may not sit on the REB.

10. REB MEETINGS

Since Polytechnique Montréal's REB receives a limited number of projects that, more often than not, are of minimal risk, the delegated review procedure described in Section 10.1 is generally applied. At Polytechnique, a significant proportion of reviews are conducted in this manner. Polytechnique's REB does not therefore have a meeting schedule, since this mode of operation allows it to make decisions within much shorter time frames. This also means that the REB conducts a full review only when one or more projects require it (at least once a year).

11. PROJECT REVIEW PROCESS

Researchers seeking to undertake a research project involving human participants must submit to the REB secretary an application for ethics review[8] by completing the lead investigator's declaration form, including a description of the proposed research, subject recruitment and participation, the benefits and harms of the research, and so forth.

The following documents are also required, according to the applicant's profile:

Professors must include:

- A copy of the **grant proposal** if the research project is funded internally (e.g., the Fondation de Polytechnique, Polytechnique Montréal Research Chair) or through a funding agency (e.g., NSERC, SSHRC, CIHR, FQRNT, FQRSC, IRSST, NIH, etc.), as well as a copy of the project funding letter of acceptance;
- A copy of the **research contract** if the project is to be carried out under contract with an industrial or other partner.
- A **detailed protocol** including literature review, hypotheses or objectives, methodology and expected results, if the research project is not funded or has not undergone a scientific assessment.

Students must include:

- The *Approbation du sujet de recherche de maîtrise* (approval of master's research topic) form (BAA ET-4) or the *Sujet de recherche et échéancier* (research topic and time frame) form (BAA-ES-ET.02F) for **master's students**;

[8] The documents to be submitted by researchers as part of their application for REB review may be found on the Research and Innovation Directorate (DRI) website.

- The *Sujet de recherche et échéancier* (research topic and time frame) form (BAA-ES-ET.02F) and the *Rapport du jury de l'examen général de synthèse* (comprehensive examination committee report) for **doctoral students**;
- A brief **project description** (including literature review, hypotheses or objectives, methodology and expected results) for all other research projects submitted for review (e.g., **UPIR grants, bachelor's students, master's students (course option), etc.**).

Other documents must also be included with the application, according to the type of research proposed:

- The **informed consent form** that provides prospective research participants with all the necessary information to make a free and informed decision;
- A **copy of the poster** or any other document that will be used to recruit study participants (if applicable);
- A **copy of the questionnaire** or any other document that will be administered to study participants (if applicable);
- In addition, if the project has received prior approval from another ethics board, researchers must provide **the letter of approval** of this REB, along with its **comments**.

On receipt of all the documentation required to review the project, the REB secretary will forward a copy to the REB members. On receipt of the file from the REB secretary, the procedures described in the sections below apply.

11.1 Proportionate approach to ethics assessment

Because research is a step into the unknown, its undertaking can involve harms to participants and to others. Potential harms may span the spectrum from minimal (e.g., inconvenience) to substantial (e.g., serious injury or emotional trauma).

The REB therefore reviews projects according to the **level of risk** they present and their ethical acceptability, taking into account **foreseeable risks**, the **potential benefits** and the **ethical implications** of the proposed research, both at the initial review stage and for the duration of the project.

In reviewing a research project, the REB considers both the foreseeable risks and all the available methods of eliminating or mitigating these risks. In all cases, the REB and researchers must protect participants against any unnecessary or avoidable risks. In its review, the REB must ensure that the potential benefits of the research always outweigh the risks and harms involved.

The REB adopts a **proportionate approach** to research ethics review such that the level of review is determined by the level of foreseeable risk for participants in the proposed research. This means that "minimal-risk" projects will be subject to **delegated review** by a select board made up of a member knowledgeable in science and another knowledgeable in law or ethics, or a member of the Polytechnique community. This select board applies the same principles and requirements as the full board. Projects deemed to be of above-minimal risk, notably those involving individuals or groups whose situation or circumstances make them vulnerable in the context of a specific research project, will be subject to a **full board review**.

11.2 Research ethics review during publicly declared emergencies

Publicly declared emergencies are extraordinary events that arise suddenly or unexpectedly, and that require urgent or quick responses to minimize devastation. In the event that research with human subjects is connected to a publicly declared emergency (e.g. natural disasters, bio-hazardous releases, large communicable disease outbreaks, etc.), the REB must give priority to these projects for review and, as far as possible, must use the delegated review process.

If a publicly declared emergency affects the operation of the REB (e.g., members are unable to meet because of the exceptional circumstances at hand), the REB will review projects submitted electronically or by phone. The REB may also call on substitute members. In all cases, the REB will ensure that the guidelines in this Policy are adhered to, as in normal circumstances.

12. REB DECISIONS

The REB shall function impartially and provide a fair hearing to the researchers who submit a research project for evaluation. The REB also encourages researchers to take part in its discussions. However, the researchers shall not be present when the REB is making its decision. Following its review of a research project, the REB can make four types of decision:

- The project is accepted, in which case the REB states its approval according to the required format (e.g., a certificate of ethical acceptability).
- The project is accepted, with conditions. In this case, the researcher is asked to provide additional information or make minor changes. The REB secretary checks that the information has been provided or that the requested changes have been made. Upon receipt of acceptable answers or corrections, the REB issues a certificate of ethical acceptability.
- The REB cannot make a decision because additional information is required to review the project. The researcher is duly informed and the review is continued at a subsequent meeting.
- The project is rejected and cannot be carried out. Before communicating this decision, the REB will inform the researcher of the grounds for refusal, giving the latter an opportunity to respond to the REB's arguments and to find a solution to the problem before a final decision is made.

The REB favours a consensual decision-making process. If, during their deliberations, REB members disagree on the acceptability of a project, they must endeavour to reach consensus, possibly by consulting with the researcher or seeking external advice. If disagreement persists, decisions will be made by a majority vote. The Chair has a deciding vote.

The REB must provide reasoned and appropriately documented opinions and decisions. The REB must communicate its decisions regarding the ethical acceptability of a research project in writing.

13. RECONSIDERATION AND APPEALS

Where researchers do not receive ethics approval, or receive approval conditional on revisions, they are entitled to reconsideration by the REB. The REB has an obligation to respond promptly. The researcher and REB should make every effort to resolve disagreements they may have through deliberation, consultation or advice. If a disagreement between the researcher and the REB cannot be resolved through reconsideration, the researcher shall have the option of appealing the REB's decision through the appeal mechanism described below.

In cases where a researcher and the REB cannot reach an agreement, having exhausted all reasonable attempts at conciliation, an appeal may be submitted to the REB secretary who will contact the REB acting as Polytechnique's appeal committee. The maximum period for submitting an appeal is thirty (30) days after the researcher receives the REB's final decision (following review or reconsideration of the project).

The REB secretary then forwards to the coordinator or secretary of that institution's REB all of the documents pertaining to the project that is the object of disagreement. The file includes: a) a cover letter, signed by the researcher and addressed to the Chair of the appeal committee, informing the latter of the decision to appeal and the main grounds of appeal; b) the documents submitted by the researcher, as well as all letters addressed to the researcher by Polytechnique's REB.

As far as possible, the following rules apply. The coordinator or secretary first notifies the Chair of the appeal committee. The latter, on verifying that the information accompanying the request is adequate and sufficient, informs the other members of the appeal REB within ten days and calls a meeting to evaluate the project submitted for appeal within a maximum of thirty days. The researcher and a representative of Polytechnique's REB must both have an opportunity to address the appeal committee, but they cannot be present during its deliberations or decision-making process. The appeal committee renders its decision within ten days following the meeting. The decision taken by this REB is final, with no possibility for appeal.

14. CONTINUING REVIEW

At the time of the initial review, the REB must determine the term of approval, and the level of continuing ethics review to be applied to the project in accordance with a proportionate approach to research ethics review. Research that involves minimal or no risk to participants should be held to the minimum requirements for continuing ethics review, that is, an annual report. The REB may request more frequent or more substantive reports if the research project is considered to pose above-minimal risk or for any other reason it may consider relevant. For research projects lasting less than one year, an end-of-study report may suffice. An end-of-study report must be submitted to the REB once the research is completed.

15. REPORTS OF UNANTICIPATED ISSUES

In the conduct of an approved research project, should unanticipated issues arise that may increase the level of risk or have other ethical implications (e.g., unexpected reactions by participants to an element of the research), the researcher shall report them to the REB in a timely manner. The researcher must then put in place all possible measures to address unanticipated incidents or issues. If the incident or issue has immediate implications for the safety of participants, the REB may withdraw ethics approval, which would require that the research be halted or modified until the matter can be addressed. Minor deviations from the research as it was initially approved, along with the means that were taken to address the issues, may be summarized in the annual report.

16. CONSENT

Respect for persons implies that individuals who participate in research should do so voluntarily (free consent), understanding the purpose of the research, and its risks and potential benefits, as fully as reasonably possible (informed consent) for the duration of the research (ongoing consent). For further details concerning the consent process, readers are advised to refer to Chapter 3 of the TCPS2.

16.1 Free consent

Free consent means that consent shall be given voluntarily and that participants may withdraw their consent at any time. In considering the voluntariness of consent, the REB and researchers should pay particular attention to situations where undue influence, coercion or the offer of incentives may undermine the voluntariness of a participant's consent to participate in research.

Undue influence and manipulation may arise when prospective participants are recruited by individuals in a position of authority (e.g., in relationships between employers and employees, or teachers and students). There may also be elements of dependency between individuals (e.g., between physician and patient or between professor and student). These relationships can impose undue influence on the individual in the position of dependence to participate in research projects. Coercion arises when a person is threatened with harm or punishment for failure to participate in a study. Lastly, incentives are anything offered to participants, monetary or otherwise, for participation in research. This Policy neither recommends nor discourages the use of incentives. However, where incentives are offered to participants, they should not be so large or attractive as to encourage reckless disregard of risks.

Moreover, each individual shall be free to participate or not in a project or to withdraw from it at any time, without having to provide any reason for doing so. The participant should not suffer any disadvantage or reprisal for withdrawing, nor should any payment due prior to the point of withdrawal be withheld. Pre-existing entitlements to care, education and other services should not be prejudiced by the decision to withdraw from a research project.

16.2 Informed consent

Informed consent means that researchers shall provide to prospective participants, or authorized third parties, full disclosure of all information necessary for making an informed decision to participate in a research project. For consent to be informed, prospective participants must understand the information that researchers provide to them. Researchers must therefore clearly explain the nature and goals of the research, and other essential information, in a manner that best promotes understanding. Prospective participants shall be given adequate time and opportunity to assimilate the information provided, pose any questions they may have, and discuss and their participation, before making a decision about participating in the project.

16.3 Ongoing consent

Ongoing consent means that consent shall be maintained throughout the research project. Researchers have an ongoing ethical and legal obligation to bring to participants' attention any changes to the research project that may affect them or their decision to continue participating in the research.

16.4 Securing consent

Subject to exceptions, a project can only begin once participants or authorized third parties (e.g., parents) have given their consent. If researchers cannot or do not want to obtain consent from prospective participants, they must justify the need for such a departure from the general requirement of consent. Consent must be maintained throughout the research project. Researchers must bring participants' attention to any changes to the research project or any incidental finding (unanticipated observation) that could affect them or their decision to continue participating in the research.

Consent is generally given in writing, except in justifiable circumstances. Evidence of consent shall be provided by means of a signed informed consent form, co-signed by the researcher. The **informed consent form** is used to communicate to participants in a research project any information that a reasonable person would consider important or even essential to make a decision about whether or not to participate in a project in a fully informed manner. It is advisable to give a copy of this document to research participants.

17. PARTICIPANTS WHO LACK CAPACITY TO CONSENT AND MINORS

The principles of respect for persons, concern for welfare and justice entail special ethical obligations toward individuals who lack capacity to consent to participate in research. This is the case of children and adults who lack legal capacity.

Minors or adults who lack capacity cannot consent to participate in research, pursuant to Section 21 of the Civil Code of Québec. Researchers must therefore seek the consent of an authorized third party who will act in the interests of the individual concerned. However, whenever possible, researchers must obtain the assent of participants who are minors or who lack capacity.

Polytechnique research projects involving minors or adults who lack capacity to give consent

must be approved and conducted according to the following procedure, in compliance with the applicable legal provisions, including Section 21 of the Civil Code of Québec.

In specific cases where research projects involving minors or adults who lack capacity must be reviewed by an ethics committee designated or appointed by the Minister of Health and Social Services, the projects must be evaluated by the designated ethics board which has jurisdiction in the place where the research is to be conducted. Such projects must also be reviewed by Polytechnique Montréal's REB in order to provide an engineering perspective.[9]

In the specific case of research projects carried out at least in part at the Sainte-Justine University Hospital Centre (SJUHC)[10], with an internal investigator who holds the status of researcher at the Sainte-Justine University Hospital Research Centre, Polytechnique researchers must submit their projects to the secretary of Polytechnique's REB and to the REB of the SJUHC. Polytechnique's REB will then transmit its comments to the SJUHC's REB, which will integrate them as far as possible before making a decision on behalf of Polytechnique's REB. Following approval for their project by the SJUHC's REB, researchers must submit to the secretary of Polytechnique's REB the comments and certificate of ethical acceptability issued by the SJUHC REB.

18. CONFLICTS OF INTEREST

Given that Polytechnique Montréal, its researchers or the members of its REB may find themselves in a real, potential or perceived conflict of interest between their duties or responsibilities related to research, and their personal, institutional or other interests, and because such conflicts of interest are likely to compromise the integrity of the research and the protection offered to participants, the institution requires prospective participants in any research project to be informed of any real, potential or perceived conflicts of interest in order to make an informed decision about whether or not to participate. The disclosure of a conflict of interest must be managed according to the context and risks, and in accordance with the institution's Policy on integrity and conflicts of interest in research.

The REB, Polytechnique and researchers must remain alert to any conflict of interest that may arise from interpersonal relationships (e.g., family or close relationships), financial partnerships, or any other interests (e.g., economic or academic). Given that a large number of research projects involve Polytechnique's industrial partners, the REB, the institution and researchers must pay particular attention to the possibility of financial conflicts of interest (e.g., financial incentives on the part of pharmaceutical or biotechnology companies, or incentives from other sponsors that may distort researchers' judgment in ensuring that projects are designed and conducted according to ethical principles. The REB, the institution and researchers must also ensure that projects funded by sponsors are designed in such a way as to respect the appropriate standards as regards the safety of participants, and that financial considerations do not compromise these standards or the scientific validity and transparency of the research process.

In all cases, Polytechnique requires that the welfare of participants take precedence over the

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[9] Research projects involving minors or adults who lack capacity that are not reviewed by an ethics committee formed or designated by the Minister of Health and Social Services must be submitted for review to MSSS Research Ethics Central Committee, known as the "Central Committee" in order to comply with the provisions of Section 21 of the Civil Code of Québec.

[10] In accordance with the collaborative agreement reached between the REBs of Polytechnique Montréal and the Sainte-Justine REB in February 2011.

interests of researchers, REB members, Polytechnique and sponsors.

18.1 REB members and conflicts of interest

The REB, as an entity, or through each of its members who make up the board, also holds trust relationships with participants, research sponsors, researchers and society as a whole. REB members can find themselves in a conflict of interest when their own research projects are under review by the REB, when they are a co-investigator, or when they are in a supervisory or mentoring relationship with a graduate student applicant who submits a project for evaluation by the REB. In such cases, the member must disclose the nature of the conflict and absent themselves from any REB discussion or decision regarding that research project.

18.2 Researchers and conflicts of interest

Researchers hold trust relationships, either directly or indirectly, with participants, research sponsors, institutions, their professional bodies and society as a whole. Researchers' conflicts of interest may arise from interpersonal relationships (e.g., family or close relationships), financial partnerships, other economic interests (e.g., spin-off companies in which researchers have stakes or research funded by companies seeking to obtain authorization to market products or technologies tested), academic interests or any other incentives that may compromise integrity or respect for the core principles of this Policy.

In such cases, researchers shall disclose in the research proposals they submit to the REB any real, potential or perceived individual conflicts of interest, as well as any institutional conflicts of interest of which they are aware that may have an impact on their research. When disclosure to the REB is not enough to manage the conflict of interest, the REB may, in accordance with the Policy on Integrity and Conflicts of Interest in Research, allow others on the research team, who are not in conflict of interest, to make decisions regarding the research project. In exceptional cases, the REB has the discretion to refuse approval of a research project where the REB decides that the conflict of interest has not been avoided or cannot be appropriately managed.

Dual roles of researchers and their associated obligations may create conflicts, undue influences, power imbalances or coercion that could affect relationships with others and affect decision-making procedures (e.g., consent of participants). This is the case when a researcher is also a teacher, advisor, consultant, supervisor, student or employer. When acting in dual or multiple roles, the researcher shall disclose the nature of the conflict to the participant in the consent process.

19. MULTI-JURISDICTIONAL RESEARCH

Contemporary research often involves collaborative partnerships among researchers from multiple institutions or countries. It may call upon the participation of a number of local populations and involve multiple institutions or multiple REBs. Multi-jurisdictional research projects include:

- A research project conducted by a team of researchers affiliated with different institutions;
- A research project conducted by a researcher affiliated with one institution, but that involves collecting data or recruiting participants at different institutions;

- A research project conducted by researchers at one institution that requires the limited collaboration of individuals affiliated with different institutions;
- A research project conducted by one or several Canadian researchers working in another province, territory or country context;
- Several research projects conducted independently by researchers affiliated with different institutions, with data combined at some point to form one overall research project.

To speed up the review of multi-jurisdictional research projects, without compromising respect for the welfare of human participants in research conducted by Polytechnique researchers, the institution has signed several agreements with other institutions. Polytechnique requires its researchers to follow the procedure below, depending on their project's level of risk and the location of the research activities:

- Research projects involving **minors that are conducted at least in part at the Sainte-Justine UHC**[11], with an internal investigator at the Sainte-Justine University Hospital Research Centre, must be submitted for review to Polytechnique's REB and to the SJUHC's REB. Polytechnique's REB will transmit its comments to the SJUHC REB, which will integrate them as far as possible before making a decision on behalf of Polytechnique's REB. Researchers therefore do not have to submit their projects for review to Polytechnique's REB. They are nonetheless required to transmit to the secretary of Polytechnique's REB the comments and certificate of ethical acceptability issued by the SJUHC's REB.

- Projects **posing minimal risk conducted at two or more Québec universities that have signed the CREPUQ agreement in this regard**[12], must be submitted for review to the REB of the lead investigator. Unless Polytechnique's REB considers the project to pose a greater-than-minimal risk, its REB will accept the decision of the lead investigator's REB. Researchers are therefore not required to have their projects reviewed again by Polytechnique's REB, but they are nonetheless required to transmit to the REB secretary the complete file submitted to the REB of the lead investigator, as well as the comments and certificate of ethical acceptability issued by that REB.

- All other research projects **posing minimal risk** are systematically subject to delegated review by Polytechnique's select ethics review board. If the research has already been reviewed by another REB, researchers must transmit the complete file submitted to the REB in question, along with the comments and certificate of ethical acceptability issued by that REB, to the secretary of Polytechnique's REB. The latter will then review the project in light of these documents.

- All multi-jurisdictional research projects **posing a greater-than-minimal risk** will be subject to (another) full board review.

20. CLINICAL TRIALS

[11] According to a collaborative agreement between the REBs of Polytechnique Montréal and the Sainte-Justine UHC in February 2011.
[12] According to the collaborative agreement signed among certain universities belonging to CREPUQ in 2011.

Clinical trials are a form of clinical research involving participants (often referred to as patients), that aims to evaluate the effects that certain products and health-related interventions have on health. Several different types of clinical trials may be carried out at Polytechnique, including on cells and other biological products, surgical procedures, radiologic procedures and medical devices or materials.

However, because clinical trials often involve large numbers of participants, and may include participants who are in vulnerable circumstances due to health issues, the risk of physical, psychological or social harm must be considered. As with other research projects involving humans, these trials must be reviewed according to the foreseeable risks and potential benefits for participants.

Polytechnique requires that its researchers, students and staff always act in the best interests of participants, making their safety a priority in the development and conduct of research projects. This means they are required to clearly inform participants about the nature of foreseeable risks and potential benefits of the research for which their participation is required. They must also inform participants of any new information that could affect their welfare or their decision to continue participating in the trial.

Polytechnique also requires that all clinical trials be registered, so as to improve researchers' awareness of similar trials previously conducted or currently under way in Canada, in order to avoid unnecessary duplication and thereby reduce the burden on participants.

Polytechnique requires its REB to review the clinical trial proposals submitted for review according to the type of trial, the phase and related ethical issues.

For more information on the different types of clinical trials, notably surgical trials and the registration of clinical trials, see Chapter 11 of the TCPS2.

21. EFFECTIVE DATE

This Policy is effective from the time it is adopted by the Board of Directors.

22. MINOR AMENDMENTS

Minor amendments to this Policy can be made by the Dean of Research and Innovation, who will inform the Assemblée de direction of the same.