DAWSON
COLLEGE

Policy for the Ethical Conduct of Research Involving Humans

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1. Introduction

Dawson College supports the conduct of research by Dawson faculty, staff, students and outside researchers, and embraces the fundamental premise that research benefits human society.

The College recognizes that, in order to maximize the benefits of research, researchers must have certain academic freedoms, including: the freedom to challenge conventional thought; freedom from institutional censorship; as well as freedom of inquiry and the right to disseminate the results of that inquiry.

It also accepts that with these freedoms comes the responsibility to ensure that any research involving humans abides by high ethical standards, and, in so doing, properly respects and protects the research participants.

Because research seeks to understand something not yet revealed, it often entails risks to research participants and others. These risks can be trivial or profound, physical or psychological, individual or social. Ethical principles and guidelines play an important role in advancing the pursuit of knowledge while protecting and respecting human participants in order to try to prevent undue risk or harm.

In Canada, these ethical principles and guidelines are defined by the Tri-Council in their *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (1998, 1st ed.; 2009, rev. draft 2nd ed.; hereafter TCPS).

This College policy abides by the TCPS and expresses Dawson's commitment to adhere to recognized standards for the ethical conduct and institutional oversight of all research involving humans.

1.1. Purpose of the Policy

The purpose of this policy is to define the ethical principles and institutional procedures that govern of conduct and oversight of all research involving humans, undertaken within the jurisdiction or under the auspices of Dawson College. It offers guidance for the interpretation of the principles of research ethics, while also identifying mandatory requirements for researchers, the College, and members of Dawson's Research Ethics Board (REB).

This document is designed to help all those who use it - including researchers, REBs (both internal and external), funders, research participants, the Dawson community, and the general public - to (a) understand and identify ethical issues in the design, conduct and oversight of research and (b) help them to arrive at reasoned and ethical responses to these issues.

Broadly speaking, the aims of this policy are to:

- Define and promote the highest possible standards for the ethical conduct and oversight of all research involving humans at Dawson; and

- Ensure the credible and proportionate review of all proposed or ongoing research involving humans.

Anyone wanting additional guidance is encouraged to contact the Coordinator of Research, or consult the full Tri-Council Policy Statement (TCPS) .

2. Scope and Application of the Policy

The principles and procedures presented in this document apply to all proposed or ongoing research projects that involve human participants, regardless of whether they are:

- Externally-funded: Research projects that are supported by one or more external funding sources and administered by the College.

- Externally-administered: Funded research projects that are administered by and granted to another institution. These projects may be led by an external researcher, and may or may not involve Dawson faculty or staff as co-investigators or collaborators.

- Independent: Research activities that are conducted locally or in collaboration with external agencies, for which no funding has been solicited or obtained.

- Internally-Funded: Research projects that have been funded using College funds or other College mechanisms of support, including release time or professional development.

The following sections define the criteria that determine whether or not a research project must be submitted to the REB for an ethics review. Though some types of research, and research-like activities, are exempt from the need to undergo REB review, Dawson College expects all research involving humans to respect the core principles and practices of ethical conduct.

2.1. Research Requiring REB Review

TCPS 1998, Article 1.1 / TCPS 2009, Article 2.1

All proposals for research involving humans must be submitted to the Dawson College Research Ethics Board (REB) for ethics review.

For the purposes of this Policy, "research" is defined as an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation. The following types of research must be reviewed by the REB:

a) Research involving human participants. Such research may involve observation, solicitation of responses, direct interaction or intervention with living individual(s) as a primary means of data collection; *or* the secondary use of identifying information from non-public records (e.g., medical or school records) or recorded data from previous studies, databases and archives, which may potentially be linked to individuals.

b) Research involving human biological fluids and materials.

Where researchers seek to collect, use, share and access different types of information or data about research participants, they are expected to determine whether the information or data proposed in research is identifiable or non-identifiable.

Privacy concerns are strongest in regard to information that identifies a specific individual. For the purposes of this Policy, information is identifiable if it, alone or when combined with other information available to the person who receives it, can reasonably be expected to identify an individual. The term "personal information" generally denotes identifiable information about an individual. For further details about the types of information and the spectrum of identifiability, refer to articles 5.6 and 5.7 of this document.

2.2. Research & Activities Exempt From REB Review

TCPS 1998, Article 1.1d / TCPS 2009, Article 2.2

The following types of **research** are not required to undergo ethics review under the TCPS guidelines.

a) Research that relies exclusively on publicly available information about individuals or institutions.

b) Research involving observation of people in public places that (1) does not allow for the identification of the individuals in research material and (2) is not staged by the researcher(s).

c) Research conducted by students in fulfillment of course requirements. Though not subject to REB review, Dawson College expects teachers and departments to ensure that student research respects the ethical guidelines defined in this policy.

The following **activities** may, in many respects resemble research, but are not considered to be research under the TCPS definition, and are exempt from the need to undergo REB review.

a) Quality assurance and quality improvement studies, program evaluations, and performance reviews or testing within normal educational requirements, when used exclusively for program review, management or improvement purposes do not constitute research for the purposes of this Policy, and do not fall within the scope of REB review.

b) Creative practice activities, meaning a process through which an artist makes or interprets a work or works of art; which may also include a study of the process of how a work of art is generated. Creative practice activities do not require review by an REB, but they may be governed by ethical practices established within the cultural sector.

   Research that employs creative practice to obtain responses from human participants that will be analyzed to answer a research question, or to generate research questions is, however, subject to REB review.

These categories may appear straightforward, but it is not always easy to determine what is or is not "research" under the TCPS guidelines, and thus to determine which projects require ethics review and which do not.

This is particularly true in regard to the types of "quality assurance" activities identified under point 2.2(d) above. The TCPS intends this article to encompass assessments of the performance of an organization or its employees or students, conducted within the mandate of the organization or as required by the terms and conditions of employment or training. Such activities are typically administered in the ordinary course of the operation of an organization.

Such activities do not normally follow the consent procedures outlined in the TCPS or this policy. However, if data collected from such activities is used later as part of a research project, this would be considered a secondary use of information not originally intended for research. Privacy concerns and questions about the need to seek consent arise when information provided for secondary use in research can be linked to individuals, and when the possibility exists that individuals can be identified in published reports or through data linkage. Privacy legislation recognizes these concerns and permits secondary use of identifiable information under certain circumstances, which are described in articles 5.6 and 5.7.

Further to the above TCPS guidelines, a discussion paper[1] by the "Ethics Unit" of Quebec's Ministry of Health and Social Services (2007) offers additional criteria for distinguishing research projects that require REB review, from similar non-research activities that are exempt. These criteria are summarized in Appendix B (Research vs. "Quality Assurance").

2.3. Uncertain Cases

TCPS 1998, Article 1.1 (discussion), p. 1.2

The opinion of the REB Chair should be sought in any instance where the researcher is unsure whether his/her project meets the above criteria for research requiring ethics review by the REB. Upon review, the Chair may determine that:

a) The project is exempt from the requirement to undergo an ethics review; or

b) The project meets the criteria for a delegated review; or

c) The project must be submitted to the REB for a full ethics review. This would occur in cases where the Chair determines that there is a degree of risk or he/she is unable to reach a definite conclusion on the matter. In this instance, the researcher shall be required to complete and submit a full "Application for REB Review" (Appendix C).

2.4. Research Prohibited at Dawson College

There are certain types of research that Dawson College cannot permit to be conducted on its premises, due to the absence of enforceable policies, and the lack of adequate space, facilities, equipment or other essential resources. This restriction applies to any research project that involves the use of:

[1] Unité de l'éthique. (2007, mai). *Note de clarification relative à la compétence matérielle et territoriale des comités d'éthique de la recherche*. Direction générale adjoint de l'évaluation, de la recherche et des affaires extérieures, Ministère de la Santé et des Services Sociaux. Retrieved January 28, from: http://ethique.msss.gouv.qc.ca/site/download.php?84358bb5a433f8504769df55b6b9f6e7

- Human remains, cadavers, embryos or foetuses;
- Animals as research subjects;
- Radioactive materials; or
- Biohazards.

Dawson's prohibition of these categories of research does not reflect any explicit or implicit value judgement on the part of the College; and it does not restrict researchers' right to become involved in such forms of research at other institutions that have the frameworks to support them. When such research is conducted outside the college by members of the Dawson community, the principles and guidelines defined in this policy and the TCPS would still apply.

If Dawson decides to support this type of research in future, this policy, and all related policies and procedures will be reviewed and updated to address the unique ethical, legal or health and safety implications of such research. All such projects would be subject to full review, by the applicable bodies.

3. Ethics Framework

In accordance with the TCPS, Dawson's research ethics framework is grounded by a set of core ethical principles and due consideration for all applicable laws of the location where the research is to be conducted.

Dawson College is accountable for all research that is conducted within its jurisdiction or under its auspices. When that research involves human participants, the College expects all those involved in its conduct, facilitation, review or oversight to recognize, understand and adhere to the principles and the laws identified in the following sections.

3.1. Core Ethical Principles

TCPS 1998, C. Guiding Ethical Principles, p. 4-7 / TCPS 2009, B. Core Principles, p. i.4-i.6

Respect for human dignity is the underlying value of the TCPS, and 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 they deserve. In the TCPS and this policy, respect for human dignity is expressed through three core principles : (1) respect for persons; (2) concern for welfare; and (3) justice.

The application of these principles is necessary to engender trust, which is an integral part of the research process. They are also complementary and interdependent, and how they apply, and the weight accorded to each, will depend on the nature and context of the research being undertaken.

It is important, above all, to recognize that an ethic of research involving human subjects should always include two essential components: (1) the selection and achievement of morally acceptable ends; and (2) the selection of morally acceptable means to those ends, (TCPS, 1998, p. i.4).

The importance of research, and the need to ensure its ethical conduct, require both researchers and REB members to navigate a sometimes difficult course between insufficient protection and overprotection of research participants. The following core principles provide the compass for that journey.

3.1.1. Respect for Persons

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

Respect for persons incorporates the dual moral obligations to (1) respect autonomy and (2) to protect those participants whose autonomy may developing, diminished or impaired (whether permanently or temporarily).

The requirement to "seek free and informed consent" is an important mechanism for respecting participants' autonomy. It underscores the principle that participation in research should be a matter of choice, and that choice must be informed, if it is to be considered meaningful.

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 potential risks or benefits, both to the participant and to others.

Respecting autonomy means giving due deference to a person's judgement, and ensuring that they are free to exercise that judgement without interference or constraint. Potential constraints may include fear of alienating those in positions of trust or authority, or consist of barriers to accessing relevant resources or knowledge outside the research context. Efforts should be made to eliminate or mitigate constraints on autonomy where possible.

While autonomy may be considered a necessary condition for participation in research, involving those who lack capacity can be valuable, just, or even necessary. For those potential research participants, additional measures are needed to protect their interests and to ensure that their wishes (to the extent that these are known), are respected. These measures will generally include seeking consent from an authorized third party who is entrusted to make decisions on behalf of the participant and/or to act out of concern for their welfare.

Even when the requirements of free and informed consent cannot be met, respect for persons requires involving the vulnerable person in decision-making, to the extent that this is possible.

3.1.2. Concern for Welfare

The welfare of a person is the quality of that person's experience of life in all its aspects. Welfare is constituted of the impact on persons of such factors as their physical, mental and spiritual health, as well as their physical, economic and social circumstances. Other contributing factors include participants' right to privacy, and to control the use of information about them, or the treatment of any human biological or reproductive materials provided by them, according to their expressed or reasonably expected wishes.

Concern for welfare requires researchers and REBs to protect the welfare of participants, and, in some circumstances, to promote that welfare. To do so, they must ensure that participants are not exposed to unnecessary risks, and must attempt to minimize the risks associated with any given research. They should strive to achieve the best possible balance of risks and potential benefits; and, in keeping with the

principle of respect for persons, must allow participants or authorized third parties to make the final judgement about the acceptability of this balance to them.

The welfare of groups can also be affected by research. Groups may benefit from the knowledge gained from the research, but they may also suffer from stigmatization, discrimination or damage to reputation. During the design process, engagement with groups whose welfare may be affected by the research can help to clarify the potential impact of the research and indicate where any negative impact on welfare can be minimized.

Researchers must also consider the risks and potential benefits of their research, and the knowledge it might generate for the welfare of society as a whole. While research on individuals may affect the welfare of a group(s), the weight given to the group's welfare will depend on the nature of the research being undertaken and the individuals or group in question. This consideration does not imply that the welfare of a group should be given priority over the welfare of individuals.

3.1.3. 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.

Fair and equitable treatment does not always mean treating people in the same way. Differences in treatment or distribution are justified when there are morally relevant differences between persons or groups. One important difference that must be considered for fairness and equity is vulnerability.

Vulnerability is often caused by limited capacity or limited access to social goods, such as rights, opportunities and power. Vulnerable persons or groups have traditionally included children, the elderly, prisoners, those with mental health issues, and those with diminished capacity for self-determination. Ethnic and racial minorities and those who are institutionalized are other examples of groups who have, at times, been treated unfairly and inequitably in research or have been excluded from research opportunities. Special protections may be required to ensure the just treatment of vulnerable or marginalized persons or groups.

The recruitment process is an important component of the fair and equitable conduct of research. Participants should be chosen based on inclusion criteria that are justified by the research question, and not simply because they are easy to access or manipulate. Inequity is created when particular groups fail to receive fair benefits from research or when they are arbitrarily excluded from research, for reasons unrelated to the research question.

Another important threat to justice is the imbalance of power that often exists in the relationship between researcher and participant. Participants will generally not understand the research in the same way and in the same depth as does the researcher. Historically, there have been instances in which this power imbalance has been abused, with resulting harm to participants.

3.2. Ethics and the Law

TCPS 1998, F. Ethics and Law, p. i.8 / TCPS 2009, Research Ethics and Law, p. 7-8

The law affects and regulates the standards and conduct of research involving human subjects in a variety of ways, such as privacy, confidentiality, intellectual property, the capacity of research participants, and in many other areas. Human rights legislation prohibits discrimination on a variety of grounds. In addition, most documents on research ethics prohibit discrimination and recognize equal treatment as fundamental.

The legal context for research involving humans is constantly evolving and differs from jurisdiction to jurisdiction. Legal and regulatory requirements may vary depending on: where in Canada the research is being conducted; who is funding and/or conducting the research; or a combination of constitutional, statutory, regulatory, common law and/or international or legal requirements of jurisdictions outside of Canada.

REBs and researchers should be aware of applicable laws in order to identify legal issues that may arise in the conduct of research. REBs may satisfy this obligation through expertise among their members or through wider consultation. The researcher may seek independent legal advice where necessary.

As a Canadian institution of higher education, operating within the province of Quebec, Dawson College expects all research projects conducted within its jurisdiction to comply with federal and provincial laws. These include:

- The Canadian Charter of Rights and Freedoms;
- The Québec Charter of Human Rights and Freedoms (R.S.Q., c. C-12);
- The Civil Code of Québec;
- An Act Respecting Access to Documents Held by Public Bodies and the Protection of Personal Information (R.S.Q., c. A-2.1);
- An Act Respecting the Protection of Personal Information in the Private Sector (R.S.Q., c P-39.1);
- An Act Respecting Health Services and Social Services (R.S.Q., c. S-4.2);
- Archives Act (R.S.Q., c. A-21.1).

4. Approach to REB Review

TCPS 1998, Article 1.5(c) / TCPS 2009, Article 2.9 (discussion) & 6.12

This section defines the parameters of the *proportionate approach* to ethics review, which is recommended by the TCPS and employed by the Research Ethics Board (REB). This approach tailors the level of REB scrutiny to the level of risk presented by the research, both at the stage of the initial review and throughout the period the research is active, in order to ensure the continued ethical acceptability of research.

A proportionate approach to ethics review begins with an assessment, primarily from the participant perspective, of the magnitude and probability of potential harms (i.e., risk) or potential benefits inherent in the research.

The importance of the participant perspective, as well as the concepts of "risk" (particularly 'minimal risk') and "benefit" are examined in this section, as are the criteria for determining the potential role of scholarly review in the REB's ethics review process.

Proportionate Approach to Ethics Review

TCPS 1998, Article 1.6 / TCPS 2009, Article 2.9

Proportionality is the approach to ethics review recommended throughout the TCPS and this policy. When conducting an ethics review, Dawson expects the REB to adopt a proportionate approach, such that: the lower the level of risk, the lower the level of scrutiny; and the higher the level of risk, the higher the level of scrutiny.

A "proportionate approach" implies different levels of review for different research proposals. However, a reduced level of scrutiny for research that poses minimal risk does not imply a lower level of adherence to the core principles, or to the quality of expertise required.

The intent of such an approach is only to reduce unnecessary impediments, and to facilitate the timely progress of ethical research.

4.1. Participant Perspective

TCPS 1998, D. A Subject-Centred Perspective, p. i.8 / TCPS 2009, The Perspective of the Participant, p. 8

In designing and conducting research or reviewing the ethics of research, researchers and REBs must be mindful of the perspective of the participant. It may be necessary to consider the context – social, economic, cultural or other – that shapes the participant's life, to properly evaluate the implications of the research in terms of the core principles.

4.2. Risks & Potential Benefits

TCPS 1998, Analysis, Balance and Distribution of Harms and Benefits, p 1.5 / TCPS 2009, Concept of Risks and Potential Benefits, p. 18-20

Because research is a step into the unknown, its undertaking can involve harms to research participants and to others. Harm is anything that has a negative effect on the welfare of participants, and the nature of the harm may take a social, behavioural, psychological, physical or economic form.

The core principle of Concern for Welfare imposes an ethical obligation to design, assess and conduct research in a way that protects research participants from any unnecessary or avoidable risks. In its review, the REB should always assess whether the anticipated research outcomes and potential benefits merit the risks; and should recognize that researchers and research participants may not see the risks and potential benefits of a research project in the same way.

For the purposes of definition, *risk* is a function of the magnitude or seriousness of the harm and the probability that it will occur, whether to the participants or other parties. A proper ethical analysis of research should consider both the risk and the available methods of mitigating the risk.

4.2.1. The magnitude or seriousness of the harm

Potential harms in research may span the spectrum from minimal (e.g. inconvenience of participation in research) through substantial (e.g. a major physical injury or an emotional trauma). Harms may be transient such as a temporary emotional reaction to a survey question, while other types of harm may be longer lasting, such as the loss of reputation following a breach of confidentiality. Research in certain disciplines, such as epidemiology, genetics, sociology or cultural anthropology, may present risks that go beyond the individual and may involve the interests of communities, societies or other defined groups.

4.2.2. The probability of occurrence of the harm

This refers to the likelihood of participants actually suffering the relevant harms. An assessment of such probability may be based on the researcher's past experience conducting such studies, or the review of existing publications that provide rates of the relevant harms in similar issues. Researchers should attempt to estimate the occurrence of the relevant harms, though this may be difficult, or not possible for new or emerging areas of research where no prior experience, comparable research, or publications exist.

Certain accepted research paradigms bring inherent limitations to the prior identification of risk. For example, when research in the social sciences employs emergent design, the manner in which the study will proceed and any associated risks may be known only as the study unfolds. (See Chapters 3 and 10).

4.2.3. Minimal Risk

Minimal risk research requires REB review, though it is often eligible for delegated review (described in article 6.3.3). For the purposes of this policy, "minimal risk" research is defined as research in which the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by the participant in those aspects of his or her everyday life that relate to the research.

In their assessment of the acceptable threshold of minimal risk, REBs have special ethical obligations towards individuals or groups whose situation or circumstances make them vulnerable in the context of a specific research project, as well as to those who live with relatively high levels of risk on a daily basis. Their inclusion in research should not exacerbate their vulnerability.

Above this threshold of minimal risk, the research warrants a higher degree of scrutiny and greater provision for the protection of the interests of prospective subjects.

4.2.4. Potential Benefits

Research involving humans may produce benefits that positively affect the welfare of society as a whole through the advancements of knowledge, for future generations, for participants themselves or for other individuals. However, much research offers little or no direct benefit to participants. In most research, the primary benefits produced are for society and for the advancement of knowledge.

4.3. Relationship Between Scholarly Review and Ethics Review

TCPS 1998, Article 1.5 / TCPS 2009, Article 2.7

As part of the ethics review process, the REB shall review the ethical implications of the research project's methods and design. The primary test to be used by REBs in evaluating a research project should be ethical probity and, where appropriate, relevant scholarly standards within the discipline of the research under review.

When conducting an ethics review, the REB should observe the following guidelines:

a) The REB shall satisfy itself that the design of a research project that poses more than minimal risk is capable of addressing the questions being asked in the research.
b) The extent of the review for scholarly standards that is required for biomedical research that does *not* involve more than minimal risk will vary according to the research being carried out.
c) Research in the humanities and the social sciences that poses, at most, minimal risk shall not normally be required by the REB to be peer reviewed.
d) Certain types of research, particularly in the social sciences and the humanities, may legitimately have a negative effect on public figures in politics, business, labour, the arts or other walks of life, or on organizations. Such research should not be blocked through the use of harms-benefits analysis or because of the potentially negative nature of the findings. The safeguard for those in the public arena is through public debate and discourse and, *in extremis*, through action in the courts for libel.

Traditions for scholarly and ethical review differ from one discipline to another, including the stage at which scholarly review occurs. To facilitate the ethics review process, researchers should demonstrate to their REB *whether*, *when* and *how* appropriate scholarly review has been, or will be, undertaken for their research. Where reasonable, they should provide the REB with the full documentation of reviews already completed.

The REB should not duplicate previous professional peer-review assessments, unless the research poses *more than a minimal risk* to participants, and there is a good and defined reason to do so. When assessing the scholarly merit of a research proposal, the REB may:

- Conclude that the proposed research has already passed appropriate peer review, for example by a funding agency;
- Establish an *ad hoc* independent external peer review;
- Establish a permanent peer review committee reporting directly to the REB;
- Assume complete responsibility for the scholarly merit, on the understanding that REB members must have the necessary scholarly expertise in the discipline to carry out a peer review of the research in question.

The REB expects researchers to provide them with full documentation of any scholarly / peer reviews of the proposed research that have been completed prior to their "Application for REB Review".

5. Consent

Free and informed consent lies at the heart of ethical research involving human subjects, and recognizes the basic right of all humans to make decisions affecting their own status and welfare. As presented in this document, the term "consent" means "free, informed, and ongoing consent," and encompasses a process that begins with the initial contact and carries through to the end of the involvement of research subjects in the project. This process refers to the dialogue, information sharing and general means through which prospective subjects choose to participate in the research.

In accordance with the TCPS, it is the duty of the REB to ensure that all research involving human subjects satisfies the following requirements respecting free and informed consent.

5.1. Consent Must Be Voluntary

TCPS 1998, Article 2.2 / TCPS 2009, Article 3.1(a)

The principle of voluntary consent means that prospective participants must be free:

a) to choose whether or not to participate in the research;
b) to withdraw from the research project at any time; and
c) to request the withdrawal of their data or biological materials.

The approach to recruitment is an important element in assuring voluntariness. In considering the voluntariness of consent, the researcher and the REB should be sensitive to situations where undue influence, coercion, or the offer of incentives may undermine a participant's voluntariness to consent to participate in research.

5.1.1. Undue Influence

Undue influence and manipulation may arise when potential participants are recruited by individuals in a position of direct authority, or one of trust and dependency (e.g. employers, teachers, physicians, caretakers, commanding officers, correctional officers, etc.).

The potential influence of power relationships on the voluntariness of consent should always be judged from the perspective of the prospective participant, since the individual being recruited may feel constrained to follow the wishes of those who have some form of control over them. Such control might be physical, psychological, financial or professional; or involve some form of inducement or threat of deprivation.

When such relationships exist between a researcher and prospective participant, the control may place undue pressure on the prospective participants. It is important that the decision of whether or not to participate in, or withdraw from, a research project not pose any threat to an individual's pre-existing status, or to his/her entitlements to care, education or other services. At the extreme, there can be no voluntariness if consent is secured by the order of authorities.

5.1.2. Coercion

Coercion is a more extreme form of undue influence, involving a threat of harm or punishment for failure to participate. Coercion would negate the voluntariness of a decision to participate or to remain in a research study.

5.1.3. Incentives

An incentive is anything which is offered to prospective participants (monetary or otherwise) in return for their participation in research. As incentives are used to encourage participation in research, they are another important consideration in assessing voluntariness. Where incentives are offered to participants, they should not be so large or attractive as to constitute an inducement to take risks that one would otherwise not take.

This policy neither recommends nor discourages the use of incentives, but places an onus on the researcher to justify to the REB the use of a particular model and the level of incentives. In considering the possibility of undue influence, researchers and REBs should be sensitive to issues such as the economic circumstances of those in the pool of prospective participants, the age and capacity of participants, the customs and practices of the community and the magnitude and probability of harms. Guardians and authorized third parties should not receive incentives.

5.1.4. Conditions of Withdrawal

The participant should not suffer any disadvantage or reprisal for withdrawing, nor should any payment due prior to the point of withdrawal be withheld. If the study used a lump-sum incentive for participation, the participant is entitled to the entire amount. If a payment schedule is used, the participant should be paid in proportion to his or her participation.

A participant may also request the withdrawal of their data or biological materials from the research record. However, in some research studies, the withdrawal of data or biological materials may not be feasible – for example, when personal information is de-identified and added to a data pool. As part of the consent process, participants should be informed, when they are entering a study, that it may not be feasible to later withdraw their data or biological materials.

5.2. Consent Must Be Informed & Ongoing

TCPS 1998, Article 2.4 / TCPS 2009, Article 3.2

At the commencement of any process of consent, researchers, or their qualified designated representatives, must provide prospective participants with all the information they will need to make an informed decision regarding whether or not to participate. The list below identifies the types of information that researchers may need to provide. Not all of the listed elements are required for all research, but additional information may be required in particular types of research or under particular circumstances. It is up to the researcher to explain to the REB why, in a particular project, some of the listed disclosure requirements do not apply.

It is the REB's responsibility to ensure that the research design includes appropriate mechanisms for obtaining the informed consent of participants; and to consider whether all the elements listed, or any additional elements, are necessary in a given research project.

The information commonly required for informed consent includes:

a) Information that the individual is being invited to participate in a research project;
b) A statement of the research purpose in plain language, including: the identity of the researcher; the identity of the funder/sponsor; the expected duration and nature of participation; a description of research procedures; and an explanation of the responsibilities of the participant;
c) A plain language description of reasonably foreseeable risks and potential benefits, that may arise from participation in the research (as well as the likely consequences of non-action, particularly in research related to treatment, or where there is a potential for physical or psychological harm);
d) An assurance that prospective subjects: are under no obligation to participate; have the right to withdraw at any time without prejudice to pre-existing entitlements; and may request the withdrawal of their data or biological materials;
e) An assurance that participants will, throughout the course of the research, receive relevant information that may influence their decision to continue or withdraw from participation;
f) Information regarding any possibility of commercialization of research findings;
g) Information concerning the presence of any apparent or real or potential conflict of interests on the part of researchers, their institutions or their sponsors;
h) The measures to be undertaken for dissemination of research results, and whether participants will be identified directly or indirectly;
i) The identify and contact information of a qualified designated representative who can explain scientific or scholarly aspects of the research;
j) The identity and contact information of qualified person(s) outside the research team who may be contacted regarding possible ethical issues in the research, or in the event of complaints or negative consequences arising from the research;
k) An indication as to who will have access to the information collected on the identity of participants, and who might have a duty to disclose such information and to whom;
l) Descriptions of how confidentiality will be protected, and anticipated uses of the data;
m) Information on any payments, including incentives for participants, reimbursements for participation-related expenses, and potential compensation for injury;
n) A statement to the effect that, by consenting, participants have not waived any rights to legal recourse in the event of research-related harm; and
o) Information regarding the circumstances under which the researcher may terminate the individual's participation in the research.

As indicated in article 5.3(e) above, it is important that participants' consent be maintained throughout their participation in the research. As such, consent encompasses a process that begins with the initial contact and carries through to the end of (and sometimes beyond) the involvement of participants in the research project. Throughout this process, the researcher has an ongoing ethical and legal obligation to bring to the participant's attention changes that have ethical implications or that may be germane to their continued participation in the research, or to the particular circumstances of the participant. In particular, researchers must disclose changes to risks or potential benefits of the research, giving the participant the opportunity to reconsider the basis for his or her consent in light of the new information.

Consistent with this requirement, researchers have an additional obligation to disclose to the participant any material incidental findings discovered in the course of research. "Incidental findings" is a term that describes unanticipated discoveries made in the course of research, which are outside the scope of the research. *Material* incidental findings are findings that have been interpreted as having significant welfare implications for the participant, whether health-related, psychological or social. If, in the course of research, material incidental findings are discovered, researchers have an obligation to inform the participant.

5.3. Consent Must Be Documented

TCPS 1998, Article 2.1(b) / TCPS 2009, Article 3.12

Evidence of consent must be obtained from each participant by the researcher, and must be recorded either in a signed consent form or in clear documentation of some other means of consent employed by the researcher.

Written consent through a signed statement from the participant is a common means of demonstrating consent, and in some instances, is mandatory (e.g. Health Canada regulations under the *Food and Drugs Act*, the Quebec Civil Code). However, there are other means of providing consent that are equally ethically acceptable.

For example, where consent is not obtained through a signed consent form, researchers may use a range of consent procedures, including oral consent, field notes, and other strategies, for documenting the consent process. Consent may also be demonstrated solely by the actions of the participant – for example, through the return of a completed questionnaire. Where there are valid reasons for not recording consent in writing, the procedures used to seek consent must be documented.

Whether or not a consent form is signed, it is advisable for the researcher to leave with the participant a written statement of the information conveyed in the consent process. However, researchers should not leave any documentation with a participant if it may compromise their safety or confidentiality, or where written documentation runs counter to prevailing cultural norms.

5.4. Capacity

TCPS 1998, Articles 2.5-2.7 / TCPS 2009, Articles 3.9-3.10

Capacity refers to the ability of prospective or actual participants to understand relevant information presented and to appreciate the potential consequences of any given decision. This ability may vary according to the complexity of the choice being made, the circumstances surrounding the decision, or the time in question. Assessing capacity is, therefore, a question of determining, at a particular point in time, whether a research participant (or potential participant) meets the bar for understanding the nature and consequences, risks and potential benefits, of a particular research project.

One may have diminished capacity and still be able to decide whether to participate in certain types of research. For this reason, researchers who choose to involve participants with low or diminished capacity should be aware of all applicable legal and regulatory requirements, which may vary among jurisdictions. Authorized third parties should also be aware of their legal responsibilities.

Subject to applicable legal requirements, the REB should ensure that individuals who are not legally competent are only invited to become research subjects when:

a) The research question can only be addressed using individuals within the identified group(s); and
b) Free and informed consent will be sought from their authorized representative(s); and
c) The research does not expose them to more than minimal risk without the potential for direct benefits for them.

The core principle of Justice presents other important ethical considerations for research involving those who lack the capacity to consent for themselves. Such research must seek an ethical balance between the vulnerability arising from participants' lack of capacity and the injustice of excluding them from the potential benefits of research.

The principles of Respect for Persons and Concern for Welfare, likewise, entail high ethical obligations towards vulnerable individuals, which often translate into special procedures to promote and protect their interests.

For research involving individuals who lack the capacity, whether permanently or temporarily, to decide for themselves whether or not to participate, the REB must ensure that, as a minimum, the following conditions are met:

a) The researcher will seek consent from the authorized third party, will show how that consent will be obtained, as well as how the participants' welfare will be protected;
b) The authorized third party shall not be the researcher or any other member of the research team;
c) The consent of an authorized third party will be required throughout the participation in research of a participant who lacks capacity to consent on his/her own behalf; and
d) When authorization for participation was granted by an authorized third party, and the participant acquires or regains capacity during the course of the research, the researcher shall promptly seek the participant's consent as a condition of continuing participation.

In cases where the legally incompetent individual understands the nature and consequences of the research, and where free and informed consent has been obtained from an authorized third party on his/her behalf, the researcher shall seek to ascertain the wishes of the potential subject concerning his/her participation. Any dissent on the part of this individual will preclude his or her participation in the research.

5.5. Departures From the General Principles of Consent

TCPS 1998, Article 2.1(c) / TCPS 2009, Article 3.7

The REB may approve a consent procedure that does not include or that alters some or all of the elements of consent or may waive the requirement to seek informed consent, provided that the REB finds and documents that all of the following apply:

a) the research involves no more than minimal risk to the participants;
b) the alteration or waiver is unlikely to adversely affect the welfare of the participants;
c) it is impossible to carry out the research and to answer the research question properly, given the research design, without the alteration or waiver;
d) whenever possible and appropriate, the participants will be debriefed and provided with additional pertinent information after participation or at a later time during the study; and

e) the altered or waived consent does not involve a therapeutic intervention, or other clinical or diagnostic interventions.

It is the responsibility of researchers to justify the need for such a departure. It is the responsibility of REBs, however, to understand that certain research methodologies necessitate a different approach to consent and to exercise judgment on whether the need for the research justifies a limited or temporary exception to the general requirements in a particular case.

It should be noted that in cases of randomization and blinding in clinical trials, neither the research participants nor the researchers know which treatment arm the participant will be receiving before the research commences. This is not regarded as a waiver or alteration of the requirements for consent, however, so long as the research participants or their authorized third parties are informed of the probability of being randomly assigned to one arm of the study or another.

5.5.1. Research Involving Partial Disclosure or Deception

TCPS 1998, Article 2.1(c)-(d) / TCPS 2009, Article 3.7

Some types of research can be carried out only if the participants do not know in advance the true purpose of the research. For example, in some research, participants may not know that they are part of a research project until it is over, or they may be told in advance about the task that they will be asked to perform, yet given additional information that provides them with a different perspective on some aspect of the task or research and/or its purpose. For such techniques to fall within the exception to the general requirement of full disclosure for consent, the research must meet the requirements defined in article 5.5 above.

Where partial disclosure or deception is used, debriefing is an important mechanism for maintaining the participant's trust in the research community. This debriefing, as referred to in Article 5.5(d), should be proportionate to the sensitivity of the issue. The researchers should give details about the importance of the research, the necessity of having to resort to partial disclosure or deception, and express their concern about the welfare of the participants. They should seek to remove any misconceptions that may have arisen and to re-establish any trust that might have been lost, by explaining why these research procedures were necessary to obtain scientifically valid findings.

In some cases – for example, in research involving children – it may be more appropriate to debrief the parents, guardians or authorized third parties rather than the participants themselves. In other cases, it may be more appropriate to debrief the entire family or community.

In studies in which a waiver of prior consent has been granted by the REB, it may still be possible for participants to express their consent or refusal at the conclusion of the study, following debriefing. In cases where a participant expresses concerns about participation in a study, the researcher may give the participant the option of removing his or her data from the project. Researchers should be required, as part of their research proposal, to set out the conditions under which they would *not* be able to remove a participant's data from the study, even if the participant requested such a withdrawal, and justify why these conditions are essential for conducting the research. If, under the terms of the research proposal, participants are not able to withdraw their data, the identity of these participants must be protected. Participants who express concern about the conduct of the study at the time of debriefing or who contest the limits imposed on withdrawing their data should be referred to the REB(s) that approved the research.

5.6. Privacy and Confidentiality

TCPS 1998, Section 3 / TCPS 2009, Chapter 5

Privacy risks in research relate to the identifiability of participants and the potential harms they, or groups to which they belong, may experience from the collection, use and disclosure of personal information. Such risks arise at all stages of the research life cycle, including the initial collection of information, its use and analysis to address research questions, the dissemination of research results, the storage and retention of information, and the disposal of records or devices on which information is stored.

Ethical concerns regarding privacy decrease as it becomes more difficult or impossible to associate information with a particular individual. These concerns also vary with the sensitivity of the information and the extent to which access, use or disclosure may harm an individual or group by exposing them to embarrassment, stigmatization, discrimination or other detriments.

When it is not feasible to use anonymous or anonymized data for research, the ethical duty of confidentiality and appropriate measures to safeguard information become paramount. There are many reasons why data may need to be gathered and retained in an identifiable form. This policy generally requires more stringent protections in research involving identifiable information.

Researchers should consult their REB if they are uncertain about whether information proposed for use in research is identifiable (for example, when proposing to link de-identified datasets).

5.6.1. Ethical Duty of Confidentiality

TCPS 1998, Article 3.2 / TCPS 2009, Article 5.1-5.2

Researchers have an ethical duty to safeguard any information that is entrusted to them, and to not misuse or wrongfully disclose it. This duty of confidentiality applies to information obtained directly from participants *or* from other researchers or institutions that have legal, professional or other obligations to maintain confidentiality.

At times, this duty must be balanced against other legal or professional requirements, or competing ethical considerations, that call for the disclosure of information obtained or created in a research context.

For this reason, researchers must describe the measures they will take to meet confidentiality obligations, and also explain any reasonably foreseeable disclosure requirements. This information must be provided:

a) in any application materials they submit to the REB; and
b) during the consent process with potential research participants.

5.6.2. Safeguarding Information

TCPS 1998, Article 3.2 / TCPS 2009, Article 5.3

When a research project involves the collection or storage of identifiable information, researchers must provide details to the REB regarding any proposed measures for safeguarding that information, over the full life cycle of the project – that is, its collection, use, dissemination, retention and/or disposal.

Factors relevant to the REB's assessment of the adequacy of the researchers' proposed measures for safeguarding information include:

a) the type of information to be collected;

b) the purpose for which the information will be used, and purpose of any secondary use of identifiable information;
c) limits on the use, disclosure and retention of the information;
d) risks of re-identification of individuals;
e) appropriate security safeguards for the full life cycle of information;
f) any recording of observations (e.g. photographs, videos, sound recordings) in the research that may allow identification of particular participants;
g) any anticipated uses of personal information from the research; and
h) any anticipated linkage of data gathered in the research with other data about participants, whether those data are contained in public or personal records. (See also Section E).

In providing support for research, Dawson College recognizes its legal responsibilities to establish appropriate institutional security safeguards.

5.7. Consent and Secondary Use of Identifiable Information

TCPS 1998, Article 3.3 / TCPS 2009, Article 5.5

Researchers who seek a waiver of consent for the secondary use of identifiable information in research (e.g., to use data originally collected for "quality assurance" purposes, as defined in article 2.2(d)), must satisfy the REB that:

a) identifiable information is essential to the research;
b) the waiver is unlikely to adversely affect the welfare of the individuals to whom the information relates;
c) the researchers will take appropriate measures to protect the privacy of individuals and to safeguard the identifiable information;
d) the researchers will comply with any known preferences previously expressed by individuals about uses of their information;
e) it is impossible or impracticable to seek consent from individuals to whom the information relates; *and*
f) The researchers have obtained any other necessary (e.g. legal) permission for secondary use of information for research purposes.

If a researcher satisfies *all* of the above conditions, the REB may approve the research without requiring consent from the individuals to whom the information relates.

5.7.1. Secondary Use & Follow-up With Participants

TCPS 1998, Article 3.5 / TCPS 2009, Article 5.6

If a researcher obtains the REB's approval to make secondary use of identifiable information without seeking consent (article 5.7), then wishes to make contact with some of the information providers to obtain additional data, the researcher must, *prior* to making contact, obtain REB approval of the plan for making contact.

In such instances, the REB must be satisfied that the proposed manner of follow-up contact minimizes risks for those involved. The proposed plan should explain who will contact individuals to invite their participation in the research (e.g. a representative of the organization that holds the individual's

information) as well as the nature of their relationship with those individuals. Researchers will need to seek consent from these individuals in order to obtain new data.

5.7.2. Data Linkage

TCPS 1998, Article 3.6 / TCPS 2009, Article 5.7

Growing numbers of databases and the advancing technological capacity to link databases present a number of new research opportunities, but also introduce new privacy risks. In particular, it is possible that linkage of de-identified or anonymized databases may permit the re-identification of individuals.

The presence of such risks means that researchers who propose to engage in data linkage must obtain REB approval prior to carrying out the data linkage. In such instances, the researchers' application for approval must clearly describe the data that will be linked, and assess the likelihood that identifiable information will be created through the data linkage.

Where data linkage involves or is likely to produce identifiable information, the REB must be satisfied that:

a) Data linkage is essential to the research; and
b) Appropriate security measures will be implemented to safeguard information.

6. Governance of Research Ethics Review

This section describes the ethics review process at Dawson College. It defines the roles and responsibilities of all those involved in ethics review and presents operational guidelines for the REB and other responsible parties, from the initial phases of ethics review, through to the end of a research project. Throughout the review process, the REB is expected to adopt an approach that is proportionate to the level of risk posed by research under review.

6.1. Responsible Parties

Dawson College is responsible for all research conducted within its jurisdiction or under its auspices, and, for this reason, expects to be informed of all research undertaken on its premises, or in its name, whether by college faculty, students or staff, or by external researchers.

Researchers can notify the College of any intent to conduct research by contacting the Coordinator of Research, in the Office of Instructional Development, and providing her with a copy of any existing research summary, proposal or completed funding application.

Further to notifying the College, it is essential that any research project involving humans be submitted for ethics review, prior to the collection, or secondary use, of any data from human participants.

Dawson College expects all those who participate in the conduct, support, review or oversight of a research project involving humans to respect the principles and procedures defined in this policy.

6.1.1. Researcher

It is the primary responsibility of the researcher to inform the College of any intent to conduct research, by contacting the Coordinator of Research in the Office of Instructional Development. This contact presents an opportunity for the Coordinator to advise the researcher of any institutional requirements that may apply to the proposed research (such as an ethics review), and for both to identify other requirements of funder(s) or collaborators.

It is the researcher's responsibility to properly inform him- or herself about any internal and external deadlines that apply to the research and may influence the timing of research activities.

If the proposed research involves human participants, he/she must complete and submit to the Research Ethics Board a full "Application for Human Research Ethics Review" (Appendix C). The REB professional and support staff will verify that the application is complete and that all elements are present, before forwarding the application to the Chair of the REB.

If a researcher is not sure whether his/her project must undergo REB review, it is his/her responsibility to obtain a written opinion on the matter from the Chair of the REB. He or she must also supply the Chair with any documentation that can aid that decision (see article 2.3).

A researcher must obtain a formal letter of Ethics Approval from the REB, before undertaking any research activities involving the collection or secondary use of data from human participants. If a researcher obtains REB approval for an ongoing (multi-year) research project, he/she must work with the REB to establish an appropriate plan of ongoing ethics review. This plan will require, at minimum, the submission of an annual report to the REB, on the ongoing research.

Whether or not a research project is subject to an REB review, Dawson College expects all researchers to abide by the core principles of ethical research, as defined in article 3.1.

6.1.2. Research Ethics Board (REB)

TCPS 1998, Article 1.2 / TCPS 2009, Article 6.3

The Research Ethics Board (REB) is an autonomous body that is mandated by Dawson's Board of Governors to review the ethical acceptability of research involving humans, when conducted by Dawson faculty, staff, students or approved external researchers.

Dawson College is served by a single institutional REB, and its mandate from the Board of Governors grants it the authority to approve, reject, propose modifications to, or terminate *on ethical grounds* any proposed or ongoing research that involves human participants and is conducted within the jurisdiction or under the auspices of Dawson College, regardless of where the research is conducted.

The REB operates according to the guidelines defined below. Its operations are financed by the Office of the Academic Dean, and administrative support is provided by the Office of Instructional Development (OID).

6.1.2.1. Composition of the REB

TCPS 1998, Article 1.3 / TCPS 2009, Article 6. 4

The Dawson College REB shall always consist of at least five members, including both men and women, of whom:

a) at least two members have expertise in the research disciplines, fields and methodologies commonly examined by the REB;
b) at least one member is knowledgeable in ethics;
c) at least one member is knowledgeable in the law (though that member shall not be the College's legal counsel or risk manager); and
d) at least one is a community member with no existing affiliation with the institution.

Each member is formally appointed to represent the perspective of one of the above categories, but all may contribute to the review process, based on their experience, expertise or knowledge in more than one of the categories above. The role of the member "knowledgeable in the law" is to alert REBs to legal issues and their implications (such as privacy issues), *not* to provide formal legal opinions or to serve as legal counsel for the REB.

In addition to the above, the College shall nominate five equally-qualified, *substitute* REB members, who may be called to serve when regular members are unable to participate due to illness, conflict of interest or other unforeseen eventualities. All regular and substitute REB members are provided with education and training to enable them to fulfill their duties.

All REB members are recruited through a public process, which is coordinated by the Office of Instructional Development (OID). Vacant REB positions are advertised on the Dawson College web site and in other academic or community sources, as appropriate. Interested candidates are asked to complete an application summarizing their qualifications and availability. Eligible candidates are selected from among these applicants, and presented to a selection committee consisting of three members. The three members will include: the REB Chair and two other members. Out of the three members, two members must be from the Dawson College community. Out of the three members, one will be a Dean. Successful candidates are appointed by the Academic Dean, on behalf of the Board of Governors.

New members are appointed for a term of one year, renewable for up to a maximum of five years, and with an open renewal thereafter. Terms of service are limited to ensure continuity, diversity of opinion and a greater distribution of knowledge and experience throughout the institution and the community. A REB member may be removed before the end of their term in cases where that member's activities are deemed to be in violation of the REB code of conduct, or damaging to the reputation of the College and its research activities. If the REB determines that a member has compromised the fairness or transparency of the research ethics review process, members of the REB may vote to remove that member. Documentation of such a violation must be presented to the Chair of the REB, and from the Chair to the board member. The Chair of the REB shall also provide such documentation to the Academic Dean, who, acting on behalf of the Dawson College Board of Governors, shall initiate the removal of the REB member.

On occasion, the REB may review a project that requires representation or expertise not available from its regular members. In such cases, the REB may appoint **ad hoc advisors** for a specific task and for the duration of the review. Though an ad hoc advisor may share experiences, knowledge or expertise that can inform the REB's decision, he or she is not an REB member and may not vote on REB decisions.

6.1.2.2. Chair of the REB

TCPS 1998, -- / TCPS, 2009, Article 6.8

The Chair provides overall leadership to the REB, and is responsible for ensuring that the ethics review process adheres to the guidelines set out below.

The Chair receives all completed "Applications for Human Research Ethics Review", and may refer applications for full or delegated review, based on his or her assessment of the risks involved. When a decision is reached through a delegated or full review, the Chair must communicate this decision to the researcher in a timely fashion.

Through each stage of an ethics review, the Chair monitors the REB's decisions for consistency, and ensures that all decisions and dissenting opinions are recorded in the minutes of REB meetings (in cases of full REB review) or in written statements submitted by delegated REB reviewers.

If the REB decides to propose modifications to a research project - that is, to grant a "conditional ethics approval" - the Chair may assess the researcher's response and determine whether it has met the REB's conditions or addressed its concerns. If so, the Chair may immediately issue a letter of Ethics Approval on behalf of the REB, and report this to members at the next meeting. If the researcher has not met the REB's conditions, or if the Chair is unsure, then he/she must refer the matter back to the full REB for discussion at the next scheduled meeting.

The Chair must maintain complete records of all projects that come under REB review, and prepare an annual report on the REB's operations. This report is submitted to the Academic Dean, who presents it to the Board of Governors. The Chair may be invited to present this report to the Board in person.

The Chair is supported in all the above tasks by the appropriate professional and administrative support staff from the college.

6.1.3. Office of the Academic Dean

The Academic Dean is the highest authority in the College with overall responsibility for research, as delegated by the Board of Governors. In matters pertaining to institutional research policies and priorities, he/she is advised by a college-wide Research Advisory Committee (RAC)[2], which is a standing sub-committee of the Dawson College Senate. In support of these policies and priorities, the Academic Dean oversees the operations of both the Office of Instructional Development (OID) and the Office of Institutional Research (OIR), which together support and/or oversee most research conducted by or within the College.

In support of ethics review, the Office of the Academic Dean ensures that the REB is provided with the administrative and financial resources it needs to successfully carry out its mandate, and fulfill its responsibilities towards the College and its researchers. At the close of each academic year, the Dean receives an annual report from the Chair of the REB, and submits it to the Board of Governors for consideration.

[2] The precise mandate and composition of the Research Advisory Committee will be defined upon approval of this policy.

As the authorized representative of the Board of Governors, the Academic Dean may refuse to permit the conduct of a specific research project, if he determines that (1) the College lacks the necessary resources or facilities to adequately support the research or (2) the research conflicts with the established mission, strategic objectives or institutional policies of Dawson College. If the Academic Dean refuses to permit a research project, the grounds for his/her refusal must be documented in writing and be communicated to the researcher at the earliest opportunity.

Though the Academic Dean may refuse to permit a specific research project, he/she may not, on ethical grounds, overrule or set aside a decision reached by the REB. The College must abide by all decisions of the REB, except in cases where a decision is appealed by the researcher, through the established appeals process (see article 7.2).

6.1.4. The Office of Instructional Development (OID)

The OID offers a range of services in support of research at Dawson. Within the OID, the Coordinator of Research provides direct support and guidance to anyone interested in conducting research within the jurisdiction or under the auspices of Dawson College. When a researcher is ready to apply for funding or to launch a research project, the Coordinator provides a central point of submission for all documentation relating to the proposed research.

If a researcher wishes to conduct research involving humans, the REB ensures that he or she understands the College's ethics review process, and is familiar with the core principles defined in this policy. When the, REB professional and administrative staff receive an "Application for REB Review", he/she verifies that all the required elements are present (i.e., the form is complete and all appendices are provided), then forwards the completed application to the Chair of the REB.

In support to the REB, the Research Ethics Board professional and administrative staff collaborate with the REB Chair to ensure that the OID is provided with complete records of the REB's activities, including files for all the research projects under REB review, and minutes of all REB meetings. The OID stores these records on behalf of the REB, and in so doing ensures the REB's accountability to Dawson College, by maintaining clear records of its decisions and operations.

6.2. Application Procedure

TCPS, 2009, Article 6.11

Any individual who wants to conduct a research project involving humans at Dawson College must submit their project for ethics review by the Research Ethics Board (REB). An official letter of Ethics Approval must be obtained from the REB prior to the commencement of any research activities that require access to participant data, or involve any form of observation, intervention or interaction with research participants.

To present a project for ethics review, researchers must complete an "Application for REB Review" and submit this application to Research Ethics Board. The REB professional and administrative staffs verify that applications are complete, and forwards them to the REB Chair who ensures their distribution to other REB members. Incomplete applications are returned to the researcher with a request to provide any missing information; incomplete applications are not submitted to the REB Chair, and will not be reviewed until or unless the researcher provides the requested information, or justifies its absence

6.2.1. The Application for REB Review

The "Application for REB Review" can be accessed online from the Research[3] page of the Dawson College web site. A complete application must include the completed form and supporting appendices.

The application form should, at minimum, provide details about the researcher(s), a summary of the research, and descriptions of the target research participants, the proposed methods for recruiting them and for obtaining informed consent. Supporting appendices should include the research proposal, copies of any participant information and consent forms, project recruitment and advertising materials, and other relevant and available documentation, as requested on the application form.

A complete checklist of required information and appendices is provided in Appendix C, and also appears on the Research web page.

6.3. Levels of REB Review

TCPS 1998, Article 1.6 (application) / TCPS 2009, Article 6.12 (application)

In practice, a proportionate approach implies different levels of REB review for different research proposals, such that the lower the level of risk, the lower the level of scrutiny; and the higher the level of risk, the higher the level of scrutiny. This approach is intended to reduce unnecessary impediments, and to facilitate the timely progress of ethical research.

As the initial recipient of all completed "Applications for REB Review", the REB Chair is trusted to assess the risks of each research project and appropriately submit it for *full REB review* (high scrutiny) or initiate a *delegated* ethics review (reduced scrutiny).

Whether the Chair prescribes a full or delegated review, it is necessary that an ethics review be appropriate to the disciplines, fields of research and methodologies of the research under review. This means that the REB or its chosen delegates must be knowledgeable in the discipline and methodologies of the project, and be able to assess the research on its own terms.

6.3.1. Full REB Review

A full REB review requires the participation of all REB members, and is the default requirement for research projects involving human subjects. A full review constitutes a higher level of scrutiny for research project that carry some degree of potential risk for participants.

A full REB review must be conducted in the following circumstances:

a) The research requires the participation of humans who are under 18 years of age, or who lack the capacity (whether temporarily or permanently) to provide free and informed consent (see article 5.4 for a discussion of "Capacity"); or
b) The research project seeks to collect identifiable information that could potentially be linked to individual participants (see Appendix A for a definition of "Identifiable Information").

[3] Dawson College **Research** page: http://www.dawsoncollege.qc.ca/?778B9FBF-FA73-4A75-AF02-DC6FAEFAABA3

Researchers should approach the ethics review process with the expectation that their project will be subject to a full REB review, and should time the submission of their "Applications for REB Review" to fulfill the internal deadlines published on the Research page of the College web site. These deadlines are synchronized with an established schedule of REB meetings.

6.3.2. Delegated Ethics Review

A delegated ethics review is conducted by two or more members of the REB. These members are selected by the REB Chair, based on their knowledge of the discipline and methodologies of the research under review. If no regular or substitute members of the REB possess the knowledge required to review the research, the Chair may delegate the ethics review to one or more qualified members of the College faculty or other recognized authorities on the subject.

A delegated ethics review may be accomplished more quickly than a full REB review, but it must uphold the same ethical principles and standards as a full REB review, and should not be seen as differing in quality or depth.

A delegated review may be conducted in the following circumstances:

a) The research is confidently expected to involve minimal risk;
b) The review deals with minimal-risk changes to approved research;
c) The review is an annual renewal of approved minimal risk research; or
d) The review is an annual renewal of *more* than minimal risk research, where the research:
    i. will no longer involve new interventions to current research participants,
    ii. does not involve the recruitment of new research participants, *and*
    iii. the remaining research activities are limited to data analysis; or
e) The researcher has provided evidence that conditions or other requirements laid down by the REB in an initial review have been met.

Any and all decisions resulting from a delegated review must be reported to the full REB at the next scheduled meeting.

If the individuals charged with conducting the delegated review differ significantly in their assessment(s) or decision(s), and if these differences cannot be resolved by them, then the project shall be referred back to the REB and required to undergo a full REB review.

6.3.3. Need for Continuing REB Review

TCPS 1998, Article 1.13 / TCPS 2009, Article 2.8, 6.14

Research projects are subject to continuing ethics review from the date of initial REB approval until the completion of the study. At the time of first review, the REB will establish the term of approval and the level at which continuing ethics review should occur, in accordance with a proportionate approach to research ethics review.

For research projects lasting longer than one year, researchers should submit at minimum an annual report with sufficient details to enable the REB to make an informed judgment about the ethical acceptability of ongoing research activities. For research projects lasting less than one year, or involving minimal to no risk, a short annual report should suffice.

Research that poses greater-than-minimal risk requires a more extensive continuing ethics review. This could include more frequent reporting to the REB, monitoring and review of the consent process, or the review of participant records and site visits. Other reporting mechanisms for continuing ethics review may be required by funders or sponsors.

The reporting schedule for continuing ethics review may be adjusted at any time during the life of the project. This would be necessary, for example, if a research project departs from an approved research plan, due to: (1) the emergence of events or issues that the researcher did not anticipate in the planning and submission phases; (2) changes the researcher decides to make to the approved research; or (3) single and unavoidable incidents.

Changes to the research plan may introduce new ethical considerations, such as an altered level of risk to participants. Researchers must inform the REB of all departures from an approved research plan; and, where possible, refrain from implementing such changes until they receive documented ethics approval for the altered plan, from the REB.

6.3.4. Scholarly Review

If a research project poses greater more than a minimal risk to participants, the REB may decide to conduct or arrange a scholarly review of the proposed research. The role of scholarly review in the ethics review process is discussed in article 4.4.

6.4. Meetings and Attendance

TCPS 1998, Article 1.7 / TCPS 2009, Article 6.10

Dawson's REB members meet face-to-face and on a regular basis, in order to discharge the duties of membership. Meetings are held at least once per month during the Fall (August to December) and Winter (January to May) academic semesters. At the start of each semester, the REB Chair polls members to establish an acceptable meeting time, then devises a regular schedule of meetings for that semester. Depending on the number and complexity of applications submitted for review, the REB Chair may need to schedule additional meetings. The REB does not meet in June or July, and does not review applications during these summer months.

From its meeting schedule, the REB Chair establishes a set of application submission deadlines for researchers. These deadlines typically fall two weeks in advance of a scheduled REB meeting, allowing members sufficient time to review applications independently, before conducting the group review. Researchers may submit applications at any time, but should note that those submitted after a given deadline will not be reviewed at the upcoming meeting; and applications submitted in the summer will not be reviewed before the next Fall meeting.

In addition to its regular meetings, REB members are expected to attend an annual general meeting, and participate in occasional retreats or workshops designed to: (1) improve the overall operation of the REB through targeted training; (2) discuss general issues/concerns arising from the REB's operations; or (3) to revise procedures and policies.

Regular attendance by REB members at meetings is important, and frequent unexplained absences should be interpreted as notice of resignation. Personal or unexpected circumstances may prevent individual

member(s) from attending an REB meeting in person. On these occasions, input may be provided by member(s) through different, but acceptable, means (such as a written submission, or the use of videoconferencing technology).

When there is less than full attendance, decisions requiring full review should be adopted only if (1) the rules of quorum have been satisfied (section 5.4.2), and (2) the members present at the meeting possess the range of background and expertise necessary to review the project.

6.4.1. Quorum

TCPS 1998, Article 1.7 (application) / TCPS 2009, Article 6.9

If the research project is submitted for full REB review, the REB may only render a decision if quorum is achieved. Quorum for Dawson's REB requires at least five members. These members must satisfy the minimum criteria for member representation as outlined in article 6.1.2.1, and must possess the specific knowledge or expertise required to conduct a competent ethics review of the proposal(s) under consideration at that meeting.

All decisions of the REB must be supported by a majority (at least 50% +1) of the members present at the meeting. Ad hoc advisors, observers, research ethics administration staff and others attending REB meetings may not be counted in the quorum for an REB.

6.5. Decision Making

TCPS 1998, Article 1.9-1.10 / TCPS 2009, Article 6.13

The REB must function impartially and provide reasoned and appropriately documented opinions and decisions. REB members should make decisions on the ethical acceptability of research in a timely manner, and communicate approvals or refusals to researchers in writing - in print or by electronic means - at the earliest opportunity.

When conducting an ethics review, the REB shall provide a fair hearing to those involved. It should accommodate reasonable requests from researchers, and may initiate invitations to researchers, to participate in discussions about their proposals, though the researchers may not be present when the REB is making its decision. When an REB is considering a negative decision, it must provide the researcher with all the reasons for doing so and give the researcher an opportunity to reply before making a final decision.

In the event that a minority within the REB membership considers a research project unethical, even though it is acceptable to a majority of members, an effort should be made to reach consensus. Consultation with the researcher, external advice, or further reflection by the REB may be helpful. If disagreement persists, a decision should be made in accordance with the process mandated by the institution. In such instances, the minority position may be communicated to the researcher.

Participation by the researcher in such discussions is often very helpful to both REBs and researchers. Such discussions may result in a deferral of the REB's decision until the researcher has considered the discussions and possibly modified the proposal. Such discussions are an essential part of the educational role of the REB.

6.6. Conflict of Interests

TCPS 1998, Section 4 / TCPS 2009, Chapter 7

Conflicts of interests must be assessed when conducting research involving humans to ensure protection of the potential participant and integrity of the research. Conflicts of interests that jeopardize these protections are contrary to the core principles on which this policy is based. In light of this, the first step is to avoid or prevent being in a condition of conflict of interests, if possible. When it is not possible to avoid such a condition, then the next step is to disclose the conflict to the appropriate persons, who will make appropriate efforts to minimize or manage the conflict of interests.

Like all members of Dawson College, Dawson researchers and REB members are expected to abide by the principles defined in the Dawson College policy on *Conflict of Interest and Nepotism*[4]. Dawson does not have a policy relating specifically to conflicts of interest in research. However, any member of an institution - whether a senior administrator, researcher, REB member or any other individual - who is aware of a potential source of personal or institutional conflict of interests that may affect a research project involving humans, should refer to the above policy for proper steps to inform the REB of such conflicts. He or she may also seek guidance from Chapter 7 of the TCPS (2009).

As pertains to their responsibilities on the REB, members must, when reviewing research proposals, disclose any real or potential conflicts of interests to the REB Chair, and, where necessary, the REB may decide that one or more of its members must withdraw from REB deliberations and decisions.

REB members are in a conflict of interests when their own research projects are under review by their REB, when they are the co-investigator, or when they are in a supervisory or mentoring relationship with a graduate student applicant. REB members may also be in a conflict of interests situation when they have interpersonal relationships or personal or financial interests in a company, labour union or not-for-profit organization that may be the sponsor of the research study, or may be substantially affected by the research. The implications of undeclared conflicts of interest are outlined above in article 6.1.2.1.

Though an REB member may be in conflict and required to withdraw, he or she may still be consulted if/when there are no other individuals on the REB with the scientific expertise relevant to the proposal under review. In such instances, the REB will record this explicitly in the minutes, and the member must not be present when the REB makes its decision.

Researchers must also disclose to the REB any real, potential or perceived individual conflicts of interests that may have an impact on their research. Upon discussion with the researcher, the REB shall determine the appropriate steps to manage the conflict of interests. The perception of a conflict may, in some cases, be as damaging as a real conflict. The REB should therefore assess the likelihood that the researcher's judgment may be inappropriately influenced or *perceived* to be influenced by private or personal interests, and should determine the level of harm that is likely to result from such influence or from the perception of undue influence. Any measures devised by the researcher and REB, to manage a real or perceived conflict, should be guided by the principles of respect for persons and concern for welfare.

[4] Dawson College. (2001, January). *Conflict of Interest and Nepotism.* Retrieved March 29, 2010, from: http://dc11.dawsoncollege.qc.ca/dsweb/Get/Document-4273/conflict_interest.pdf

6.7. Record Keeping

TCPS 1998, Article 1.8 / TCPS 2009, Article 6.16

The REB must act, and be seen as acting, in a fair and reasonable manner. For this reason, the REB is required to prepare and maintain comprehensive records of its activities. These records should include: all available documentation on projects submitted for REB review; records of attendance at all REB meetings; and accurate minutes that reflect research ethics decisions.

Minutes and other relevant documentation should be accessible to authorized representatives of the institution, researchers, and to sponsors and funders, when appropriate, to assist with internal or external audits, support research monitoring or facilitate reconsideration or appeals.

The REB's records are stored in the Office of Instructional Development (OID), and the REB Chair works with the appropriate professional and administrative REB support staff to ensure that they are complete.

In addition to documenting the REB's operations, the research ethics administration (led by the OID) maintains general records relating to the REB's membership and the qualifications of its members (e.g. copies of curriculum vitae, records of participation in training).

6.7.1. REB Minutes

The minutes of REB meetings should clearly document the REB's decisions, as well as any dissents and the reasons for them. These positions should be supported by clear references to supporting documentation (i.e., documents or progress reports received and reviewed). The minutes should, likewise, record any conditions or limitations attached to REB approval, describe plans for continuing ethics review, and document the REB's treatment of any departures from approved research plans.

When the REB denies ethics approval for a research proposal, the minutes shall include the reasons for its decision.

6.7.2. Project Documentation

For each research project that is submitted for REB review, the REB should maintain a file which includes:

a) The original "Application for Human Research Ethics Review", including the original project proposal, sample consent forms, research instruments, etc.;
b) All correspondence between the researcher and the REB Chair or other REB members or delegates;
c) Letters granting or denying ethics approval;
d) Plans for continuing ethics review (e.g., multi-year projects); and any
e) Progress or annual or final reports submitted to the REB by the researcher.

6.8. Multi-Jurisdictional Research

TCPS 1998, Article 1.14 / TCPS 2009, Article 8.3-8.4

Research involving humans may require the involvement of multiple institutions and/or multiple REBs. For example, a research project may be designed/structured in any of the following ways:

a) a research project conducted by a team of researchers affiliated with different institutions;
b) several research projects conducted independently by researchers affiliated with different institutions, with data combined at some point to form one overall research project;
c) a research project conducted by a researcher affiliated with one institution, but that involves collecting data or recruiting research participants at different institutions;
d) a research project conducted by a researcher who has multiple institutional affiliations (e.g. two universities, a university and a college, or a university and a hospital);
e) a research project conducted by a researcher at one institution that requires the limited collaboration of individuals affiliated with different institutions or organizations (e.g. statisticians, lab or X-ray technicians, social workers and school teachers); or
f) a research project that researcher(s) working under the auspices of a Canadian research institution conduct in another province, territory or country.

6.8.1. Multicentred Research

Dawson College is responsible for all research conducted within its jurisdiction or under its auspices, and the REB is tasked with ensuring the ethical acceptability of any research involving human participants.

When a research project is conducted across multiple institutions (as in the situations above), it may be subject to ethics review by multiple REBs. At present, Dawson is not party to any formal agreements that would authorize another institution's REB to review applications, or grant Ethics Approval, on behalf of Dawson's REB. Any project involving human participants and conducted at Dawson College, or in its name, must be submitted for ethics review by Dawson's own REB.

If a researcher has obtained "Ethics Approval" from another REB, this approval may factor into the Chair's decision to recommend a delegated ethics review of his/her project. However, ethics approval from another REB does not replace the need for an autonomous review by Dawson's own REB.

Though the REB is required to undertake an independent review of a multicentred project, it may wish to collaborate with other REBs to facilitate the review process. This may involve communication over specific concerns and/or questions about other REBs' perspectives.

In multicentred research, the ethics review process and any special attempts to coordinate the work of separate REBs, can be facilitated if the researcher:

a) Provides information on each of the institutional REBs that will consider the project; and/or
b) Distinguishes between core elements of the research (those which cannot be altered without invalidating the pooling of data from participating institutions), and those elements that can be altered to comply with local requirements, without invalidating the data collected.

6.8.2. Research in Other Jurisdictions or Countries

As in the case of multicentred research, Dawson College recognizes that it is responsible for ensuring the ethical acceptability of research conducted by its faculty, staff or students, regardless of where the research is being conducted.

For this reason, it is necessary for research conducted outside of the College's jurisdiction - whether at another institution, outside of the province, or outside of Canada - to undergo ethics review, and that it be approved by, both (a) the REB, and (b) the REB of the host institution where the research is to be done. (If there is no REB, the project must be reviewed and approved by whatever agency has legal jurisdiction over, and equivalent ethical and procedural safeguards in place at the location where the research is to be done).

It is the researchers' responsibility to inform him or herself about any variations in the law or ethical principles which may affect his/her research in another jurisdiction, region or country.

In order to grant Ethics Approval, the REB must ensure that:

a) The project meets the regular, ethical standards applied to research conducted within its own jurisdiction; and
b) The project has been approved by an authorized local body, where the research is to be conducted.

6.8.3. Emergency Situations

TCPS 1998, Article 2.8 / TCPS 2009, Article 3.8

This section describes the protocols that the REB, the researcher and the College should observe when faced with decisions about research in emergency situations.

6.8.3.1. Individual Medical Emergencies

Dawson College does not currently engage in or support the conduct of biomedical research on its premises. However, it recognizes the some researchers may become involved with such research at other institutions. Under these circumstances, the College expects its researchers to adhere to the following guidelines for the conduct of research during individual medical emergencies.

Subject to all applicable legislative and regulatory requirements, research involving emergency health situations shall be conducted *only* if it addresses the emergency needs of individuals involved, and then only in accordance with criteria established in advance of such research by the REB. The REB may allow research that involves health emergencies to be carried out without the free and informed consent of the subject or of his or her authorized third party if ALL of the following conditions apply:

a) A serious threat to the prospective subject requires immediate intervention; and
b) Either no standard efficacious care exists or the research offers a real possibility of direct benefit to the subject in comparison with standard care; and
c) Either the risk of harm is not greater than that involved in standard efficacious care, or it is clearly justified by the direct benefits to the subject; and
d) The prospective subject is unconscious or lacks capacity to understand risks, methods and purposes of the research; and

e) Third-party authorization cannot be secured in sufficient time, despite diligent and documented efforts to do so; and
f) No relevant prior directive by the subject is known to exist.

When a previously incapacitated subject regains capacity, or when an authorized third party is found, free and informed consent shall be sought promptly for continuation in the project and for subsequent examinations or tests related to the study.

6.8.3.2. Publicly Declared Emergencies

TCPS 2009, Article 6.20

Public emergencies are extraordinary events that arise suddenly or unexpectedly and require urgent or quick responses to minimize devastation. Examples include hurricanes and other natural disasters, large communicable disease outbreaks, catastrophic civil disorders, bio-hazardous releases, environmental disasters and humanitarian emergencies. They tend to be time-limited, but may severely disrupt or destroy normal institutional, community and individual lives.

Dawson College does not currently have an institutional "Emergency Preparedness Plan" to guide its responses in the event of a publicly declared emergency. However, in previous instances (e.g., the 2009 threat of an influenza pandemic), the College has swiftly applied official directives of federal, provincial or municipal authorities; while striving to maintain regular operations, and uphold existing agreements with College employees and students.

Under such circumstances, it is the College's priority to distinguish functions that are critical to the institution's operation, from those that can be suspended or delayed. As such, research ethics review should be proportionate to the necessities occasioned by the emergency, and be governed by the interplay between public urgencies, essential research, and a continuing commitment to the core principles of ethical research, even in the face of acute public necessity.

In the event of a public emergency, the College and REB will consider the following elements when devising a plan to prioritize REB reviews:

a) what constitutes "essential" research during the emergency;
b) the initial review process of new research projects arising from the emergency (e.g. research involving interviews with first responders and victims to understand human response during a disaster, such as a tornado or earthquake);
c) continuing ethics review of research undertaken prior to the occurrence of the emergency; and
d) the review process for departures from approved research, because new information may become available very rapidly during emergencies (see article 5.5).

The REB's procedures and schedule of meetings may be adjusted to address the timing, locale, expertise, form and scope of review. Such adjustments may be prescribed by the College, under the authority of the Academic Dean, or be recommended by the REB Chair, in consultation with REB members, researchers, or research support personnel.

It is important to note that research ethics review during, or regarding, public emergencies, may require even greater care and scrutiny, since everyone (research participants, researchers and REB members themselves) may be rendered more vulnerable by the nature of the emergency. However, The College recognizes that the regular requirements for consent may not apply to research undertaken *by* federal,

provincial and territorial public health officials operating under statutory powers during public health emergencies.

Any modifications that are made in the application of the College's research ethics policies and procedures, during an officially-declared public emergency, will cease to have effect as soon as is feasible, after the emergency has ended.

7. Reconsideration & Appeals

Where researchers do not receive ethics approval upon initial review, or receive approval with conditions that they find compromise the feasibility or integrity of the proposed research, they are entitled to reconsideration by the REB. If that is not successful, they may appeal to a separate review body.

7.1. Reconsideration

TCPS 1998, 1.10 / TCPS 2009, Article 6.17

Researchers have the right to request, and the REB has an obligation to provide, reconsideration of decisions affecting a research project.

Following principles of natural and procedural justice, the REB must (a) provide researchers with reasonable opportunities to be heard, (b) present reasoned grounds for its decisions, and (c) give researchers the opportunity for rebuttal (see article 6.3.2). The REB and the researcher should make every effort to resolve any disagreements they may have through deliberation, consultation or advice.

If the decision was made by means of a delegated REB review, the researcher's original application and his/her request for reconsideration should be submitted to the REB Chair for a review by the full REB.

All requests for reconsideration should be submitted to the REB Chair no later than 30 working days (approximately 6 weeks) after the REB has issued a letter which either (a) denies ethics approval to the research project, or (b) proposes modifications to the project as a condition of obtaining ethics approval.

In any request for reconsideration, the onus is on the researcher to justify the grounds on which he/she is making the request, and to identify any breaches in the ethics review process or elements of the REB decision that are incongruous with ethical principles, as defined in this Policy.

If a satisfactory resolution cannot be reached by the researcher and REB within a period of 60 working days (approximately 12 weeks) following the researcher's request, he/she shall have the option of appealing the REB decision through the following appeal mechanism (see article 7.2).

7.2. Appeals

TCPS 1998, Article 1.11 / TCPS 2009, Article 6.18 / TCPS2 2010, Article 6.19

If the reconsideration process has been exhausted, and the REB has issued a final decision, a researcher has the right to request an appeal of that decision.. It must be stressed that the appeal process is not a

forum to merely seek a second opinion, and does not replace the need for the REB and researcher to work closely to ensure high-quality, ethical research.

In accordance with the TCPS2, the Dawson College REB shall request another institution's established REB to act as an ad hoc Research Ethics Appeals Board (REAB). The REAB shall reflect a similar range of expertise and knowledge to that of the Dawson College REB. That REAB shall also meet the procedural requirements of the TCPS2 (2010). Such an ad hoc appointment will be based on an official agreement clarifying the responsibility of the institutional review board for the ethical acceptability of the research. The researcher must provide all relevant documentation to the REAB and is obliged to act in accordance with the decisions of that Appeals Board.
If no resolution is possible, and the researcher chooses to appeal a decision by the REB, he or she must submit a written request to the Academic Dean. This request must clearly explain the grounds for the appeal, and provide available evidence for any claim(s) relating to:

a) the content of the REB's decision;
b) a breach in the ethics review procedure;
c) a perceived conflict of interests on the part of an REB member(s); or
d) disagreements regarding interpretations of this policy or the TCPS principles.

The researcher's request should be accompanied by copies of his/her original *Application for Human Research Ethics Approval* (including all supporting documentation), as well as copies of all correspondence between the researcher and Dawson's REB.

Upon receipt of such a request, the Academic Dean will transmit it, along with all supporting documentation, to the Secretary of the Appeals Board. The Secretary will respond with notification of the date when the researcher's appeal will be considered. The Appeal Board will review only those documents which are submitted as part of the researcher's request. If the REAB regular procedures allow for it, both the researcher and a representative of Dawson College REB shall be granted the opportunity to address the Appeal Board. Neither shall be present when that Appeal Board deliberates and makes a decision.

Where necessary, the Appeal Board may seek the advice of external specialists with expertise in the discipline of the research under review, but it must notify Dawson College if it does so. Any costs incurred by such consultation(s) will be assumed by Dawson College. When reviewing a researcher's case, the Appeal Board will apply the same procedures that it observes when serving in its regular capacity as a Research Ethics Board serving its institution.

Following its review, the Chair (président(e)) of the Appeal Board will have fifteen (15) working days to send a written notice of its decision to both the researcher and the Academic Dean at Dawson College. The researcher's request and all documentation relevant to the case will be returned to the secretary of Dawson's REB, in a package marked 'confidential'. He/she will file these documents in accordance with regulations surrounding the management of REB records.

The decision of the Appeal Board will be binding upon both the researcher and Dawson College. Any responsibilities arising from the Board's decision, including those of a legal nature, will fall to Dawson College.

No appeals may be submitted to the project's funding or sponsoring agency.

Appendix A. Glossary

This section provides definitions of terms that are commonly used in the process of ethics review.

Competence: The ability of prospective subjects to give informed consent in accord with their own fundamental values. It involves the ability to understand information presented, appreciate the potential consequences of the decision, and provide free and informed consent.

Confidentiality: The expectation that information communicated in the context of a special relationship will be held in confidence or kept secret.

Ethics Review: The process by which principles of ethics are applied to research involving human subjects.

Identifiable Information: Information is identifiable if it, alone or when combined with other information available to the person who receives it, can reasonably be expected to identify an individual. The term "personal information" generally denotes identifiable information about an individual. Personal information may include information about personal characteristics such as culture, age, religion and social status, as well as their life experience and educational, medical or employment histories.

> **Directly identifying information:** The information identifies a specific individual through direct identifiers (e.g. name, social insurance number, personal health number).
>
> .....
>
> **Indirectly identifying information:** The information can reasonably be expected to identify an individual through a combination of indirect identifiers (e.g. date of birth, place of residence or unique personal characteristic).
>
> .....
>
> **De-identified/coded information:** Direct identifiers are removed and replaced with a code. Depending on access to the code, it may be possible to re-identify specific research participants (e.g. participants are assigned a code name and the principal investigator retains a list that links the code name with the participant's actual name so data can be re-linked if necessary).
>
> .....
>
> **Anonymized information:** Information is irrevocably stripped of identifiers, and a code is not kept to allow future re-linkage.
>
> **Anonymous information:** Information never had identifiers associated with it (e.g. anonymous surveys).

Minimal Risk: A situation in which the probability and magnitude of possible harms associated with the research are no greater than those encountered by the subject in those aspects of his or her everyday life that relate to the research. This evaluation should be made from the perspective of the research subject.

Participants: Those individuals whose data or responses to interventions, stimuli, or questions by the researcher are relevant to answering the research question. This term encompasses those who are involved directly in research as participants, and also those who are participants because their personal data, or human biological or reproductive materials are used in research.

Privacy: The claim of individuals, groups or institutions to determine for themselves when, how, and to what extent information about them is communicated to others.

Proportionate Approach: The attitude that the more invasive the research, the greater the care should be in assessing the research.

Research: An undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation. This definition expresses the underlying aim of most research, which is to "extend knowledge", and is inclusive of the many different, but always deliberate, methods used by research in diverse academic, social or scientific disciplines .

Researcher: A researcher is any individual involved in the conduct of an approved research project.

Vulnerable Persons: Persons whose situation or characteristics may make them unable to provide free and informed consent to participate in research. This group includes children, institutionalized persons, those who have cognitive impairments, and those in a position of inferiority.

Appendix B. Research vs. "Quality Assurance"

On this topic, the TCPS (2009) states only that:

Article 1.1(d) [equivalent to 2.2.3] indicates that studies related directly to assessing the performance of an organization or its employees or students, within the mandate of the organization or according to the terms and conditions of employment or training, should also not be subject to REB review. However, performance reviews or studies that, contain an element of research in addition to assessment may need ethics review. (p. 1.2)

This passage offers little information, and the lack of TCPS guidance on these matters is addressed by the ProGroup, in its aforementioned report on the public consultations regarding the definition of research. Recognizing the increasing difficulty of distinguishing the "...boundary between investigations...requiring research ethics review and those which do not...," (2008, p. 4), this ethics panel subgroup made the recommendation that:

...a determination of the intended purpose of the activity, as distinct from the use of potentially similar methods (for example, interviews or surveys) is the key for differentiating the activities that require review by an REB and those that do not. (p. 4, emphasis added)

This recommendation is consistent with a similar set of recommendations[5] on the matter, produced by the Ethics Unit (Unité de l'éthique), of the Quebec Ministry of Health Services and Social Services. These recommendations are summarized in the insert below. A detailed table of definitions can be found in the original source.

Research vs. "Quality Assurance"
This insert proposes some ways to distinguish quality assurance and *other* mandated institutional investigations, from projects that bear the label of "research".

	Research	**Quality Assurance (QA)**
Assumptions /Premises (Présupposé)	Research is undertaken on the premise that what currently exists is not the best that *could* or should be, and that a better method or approach has yet to be discovered.	QA studies are based on the premise that the object being evaluated (e.g., a program or policy) is *already* the way it should be.
Primary Objective (Objectif premier)	The primary objective of research is to contribute or add to a knowledge base, or to confirm (validate) existing knowledge.	The primary objective of QA is to *improve* the object under investigation. It examines a situation at a given time, and assesses it from the perspective of effectiveness, relevance, efficiency and/or outcomes.

[5] Unité de l'éthique. (2007, mai). *Note de clarification relative à la compétence matérielle et territoriale des comités d'éthique de la recherche*. Direction générale adjoint de l'évaluation, de la recherche et des affaires extérieures, Ministère de la Santé et des Services Sociaux. Retrieved January 28, from: http://ethique.msss.gouv.qc.ca/site/download.php?84358bb5a433f8504769df55b6b9f6e7

Execution (Exécution)	Research has value that is extrinsic to the institution: it does not fulfill an institutional obligation, and tends to be **limited in time**.	QA has intrinsic value to an institution: it is typically undertaken **to fulfill an institutional obligation** to ensure high quality services/programs, and is, therefore, undertaken on a **regular or continuous basis**.
Relevance/ Application of Results (Portée des résultats)	Research *may* focus on a particular environment or situation, but, more frequently aims to produce results that are **relevant / generalizable to other contexts**.	QA tends to focus on a particular environment, and its results have **limited application to the context under review**. *QA does not seek or expect to produce results that are generalizable to other contexts, outside of the one investigated.*
Use of Findings / Results (Utilité des résultats)	Research findings do not typically result in immediate action, and must usually be verified / replicated by other researchers in order to be accepted and produce a deeper understanding of the topic.	QA results can have an immediate impact on a local environment, if decision makers choose to act on a project's findings.
Dissemination of Findings (Diffusion des résultats)	Research is typically undertaken with the **specific intent to disseminate the results** to a wide audience, e.g., the broader scientific community.	QA findings are generally disseminated only at a local level, to those individuals or bodies that are directly affected by them.

Appendix C. Application for REB Review, Contents Checklist

DAWSON
COLLEGE Review

Applicant Name: .....
Establishment/Organization:
Contact Info (Tel., email):
Submission Deadline Date:
Application received by (email, mail, hand-delivery):

Please complete as many fields of this form as possible.

Description	Received	Notes
Cover letter		
Application for HRE Approval Form		
Principal Investigator(s) Info		
Co-Investigator/ Collaborator Name 1 Info		
Co-Investigator/ Collaborator Name 2 Info		
Co-Investigator/ Collaborator Name 3 Info		
Title of research project		
Description of research: Abstract		
Sample of persons to be studied (i.e., participants)		
Methods of recruiting participants		
Methodology for acquiring informed consent		
Conditions of participation: Disclosure of intended deception (if applicable)		
Assessment of possible risk to participants		
Description of support mechanisms, if possible risk to participants is involved		
Description of participant debriefing (post-research)		
Other ethical concerns which may arise from this research		
Appendices:		
A copy of the research proposal associated with this request		
A copy of the ethics approval from parent organization *		
A copy of participant consent form (French, English) Category: Managers, Professionals, Support Staff, Student, Faculty		
Invitations to participants (if applicable)		
A written copy of the disclosure of research and participation statement		
Advertising materials (if applicable)		
A copy of the research instrument(s), including any question(s) and/or questionnaire(s) to be administered to participants: questions		
*** If not available at time of submission of application, HREC approval will be conditional pending receipt of parent organization's ethics approval.**		
Reviewed by:	Date:	

Sept 09

Appendix D. REB Review Process