Policy for the Ethical Conduct of Research Involving Human

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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.

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

- Animals as research subjects;
- Radioactive materials; or
- Biohazards.

Dawson's prohibition of these categories of research does not reflect any explicit or implicit value judgment 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. i.7 - i.14; 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

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

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

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
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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 atmosphere 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.

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

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 co-0.8 (d)9.6 (n 6 (h)-06 (c)-4.0.9 (e)-6 (d)-0.8 q)9.6 (nu t)]TJ -0.001 TJ -0134 Tw 196957 0

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 (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

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 reidentification 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 insee dd Sh.152 0 Td6 (al)1ae fushcos;

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 researcher's 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. [illegible]

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 (although 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

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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 RE9dw 7.663 0 Td (-1.31.217 TD 0.623)-6

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6.2.1. The Application for REB Review

The "Application for REB Review" can be accessed online from the Research 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 to assess the risks of each research project and appropriately submit 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 R d2d [(re)-3 (v)eview9 (t)7.9 luire rn o oonoaryreduaryre

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

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

6.7. Record Keeping

6.8. Multi-Jurisdictional Research

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

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).

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

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 TCPS 2, 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 TCPS 2 (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 interest on the part of an REB member(s); or
d) disagreements regarding interpretation 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 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 B Research vs. “Quality Assurance”

On this topic, the TCPS 2 (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), evie4n p. 4e9v6 (v)-Telor(71g7 (136-0.7 (e) t1.7 (r)s.s4a Tc 8eleth.t fTc 0 T(i)2[(ov)-33 nt1.7 (r)a

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Appendix D. REB Review Process