

Benchmarks for the ethics review of course-based research activities carried out by college students

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Legal Deposit
Bibliothèque et Archives nationales du Québec, 2021
ISBN : 978-2-921819-55-8 (PDF version)
987-2-921819-57-2 (printed version)

How to cite this document:
Bouchard, N. N., Briand, M., Dumas, M.-C. and Lapostolle, L. (2021). *Benchmarks for the ethics review of course-based research activities carried out by college students*, Association pour la recherche au collégial. <https://eduq.info/xmlui/handle/11515/38170>

This guide was developed thanks to a Secretariat on Responsible Conduct of Research Education and Training Support Grant, awarded by the Interagency Advisory Panel on Research Ethics and the Panel on Responsible Conduct of Research on behalf of the three federal research funding agencies: the Canadian Institutes of Health Research, the Natural Sciences and Engineering Research Council of Canada and the Social Sciences and Humanities Research Council, and to a grant from the Canadian Relations Support Program of the Secrétariat du Québec aux relations canadiennes.

Également disponible en français [<https://eduq.info/xmlui/handle/11515/38169>]



Abbreviations

- REB** Research Ethics Board
- TCPS** *Tri-Council Policy Statement: Ethical Conduct for Research*
- CORE** Course on Research Ethics

Introduction

The most recent version of the TCPS 2, published in 2018, sets out the expectations around the review of course-based research activities that have a pedagogical purpose and are carried out by students. In fact, such activities require an ethics review under the Tri-Council Policy, even if the students do not typically do research that is defined as “an undertaking intended to extend knowledge through a disciplined inquiry and/or systematic investigation” (p. 220). This type of activity gives students an opportunity to familiarize themselves with research methods and current requirements, such as responsible conduct or ethics, rather than to advance knowledge in a specific field. While the guidelines outlined in the TCPS 2 (2018) are clear in certain settings, they are not necessarily easy to apply in the context of college education.

At the college level, where students are only just being initiated to research, applications that must be submitted to a Research Ethics Board (REB) for review can be difficult to prepare. Furthermore, college professors are not required to conduct research, which can make it even more difficult for them to guide students through what many recognize as a challenging process. A large number of colleges have REBs or cross-institutional agreements for the ethics review of research projects. However, the review of research activities with a pedagogical purpose may impose heavier workloads and strict deadlines, making it difficult to implement the procedures outlined in the most recent version of the TCPS 2 (2018).

This document provides an overview of the TCPS 2 (2018) with respect to commonly observed realities in four main areas: the review processes for research activities carried out by students, including the specifics of a possible delegated review for course-based activities; consent; commitment to confidentiality and privacy; and research risks. It also proposes an interpretation of the issues related to the applicability of this framework to college education. With these issues in mind, the authors share ideas to help support the process of creating administrative mechanisms and developing educational approaches to assist the ethics review of student-led research activities. It also served as a support tool during the session offered by the Association pour la recherche au collégial on September 23, 2021. This document began to take shape during the course of preparations for the application of the TCPS 2 (2018) requirements regarding the review of pedagogical research activities conducted by students at Cégep de Granby, Cégep de Jonquière and Cégep Garneau, and was completed with great care and conviction!

Premises

- 1 In the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (2018), research is defined as an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation.
- 2 All course-based research activities must be evaluated. The 2018 edition of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2* is clear in this regard.
- 3 Scientific literature on research activities carried out by students as part of a course reveals ethical breaches in the projects being conducted.
- 4 Colleges that have signed the Agreement on the Administration of Agency Grants and Awards by Research Institutions have an obligation to comply with the requirements set out in the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (2018) and the *Tri-Agency Framework: Responsible Conduct of Research* (2016).
- 5 The Research Ethics Board takes a proportionate approach to ethics review and may delegate the review of projects involving minimal risk.
- 6 All individuals involved in research, whether they are researchers, professors, or members of a research ethics board, for example, must put themselves in the position of the participants since they are the ones who bear the primary risks of the research.

Methods of evaluation

SCHEMA 1

The ethics review of course-based and minimal-risk research activities carried out by college students may be delegated to reviewers who are non-members of the REB, under certain conditions.

Consent

SCHEMA 2

In research, respect for persons is expressed principally through the securing of free, informed and ongoing consent of participants, since they are the ones who bear the primary risks of the research.

Aspects

Confidentiality

SCHEMA 3

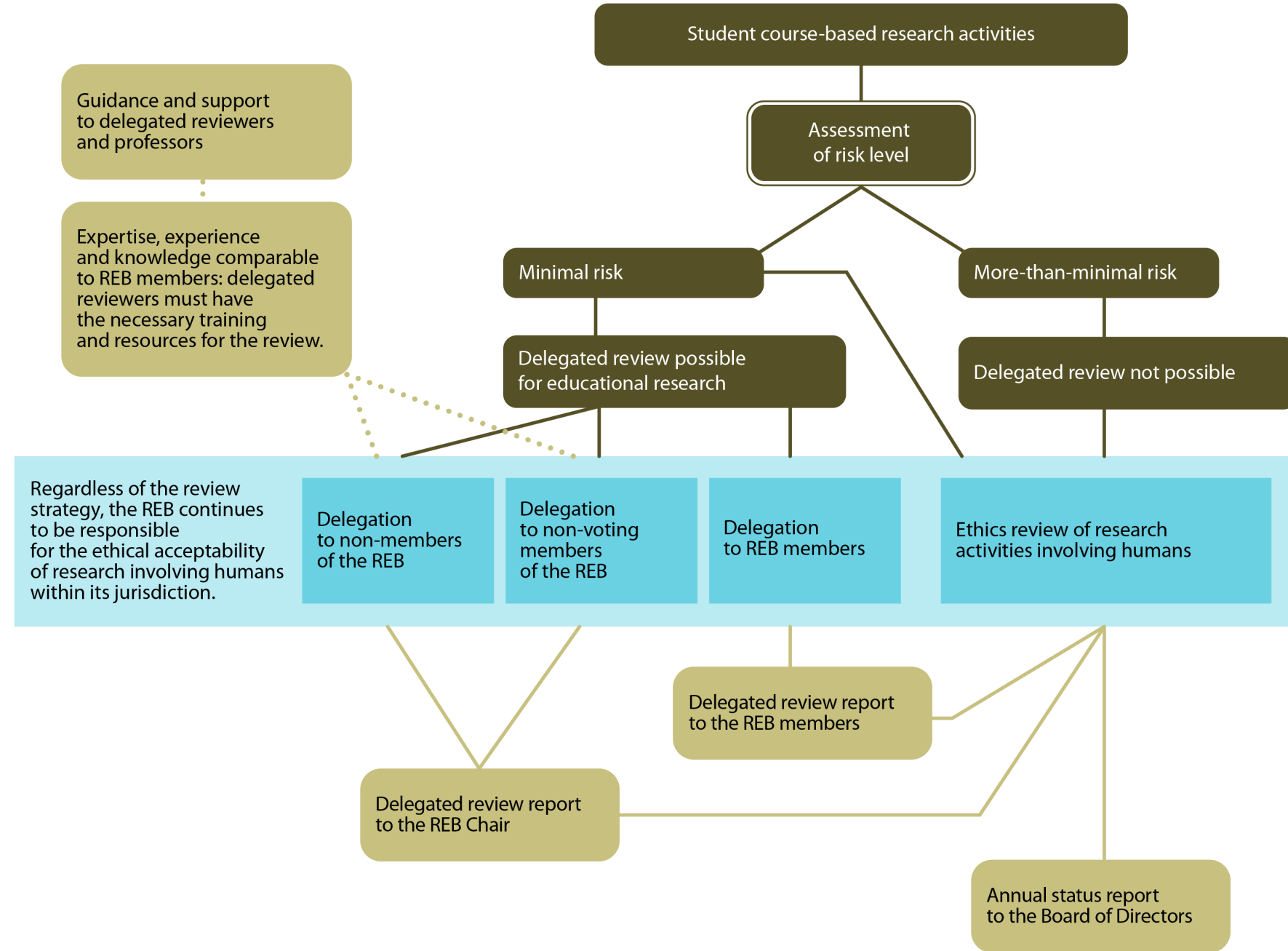
Students have a duty to treat personal information in a confidential manner and are expected to adopt robust practices at all stages of the research to minimize risks to the privacy of participants.

Risks

SCHEMA 4

The identification of all foreseeable risks that may result from participation in a research activity helps to determine the level of risk and, as a result, the measures that students must commit to undertaking with regard to participant welfare.

Methods of evaluation



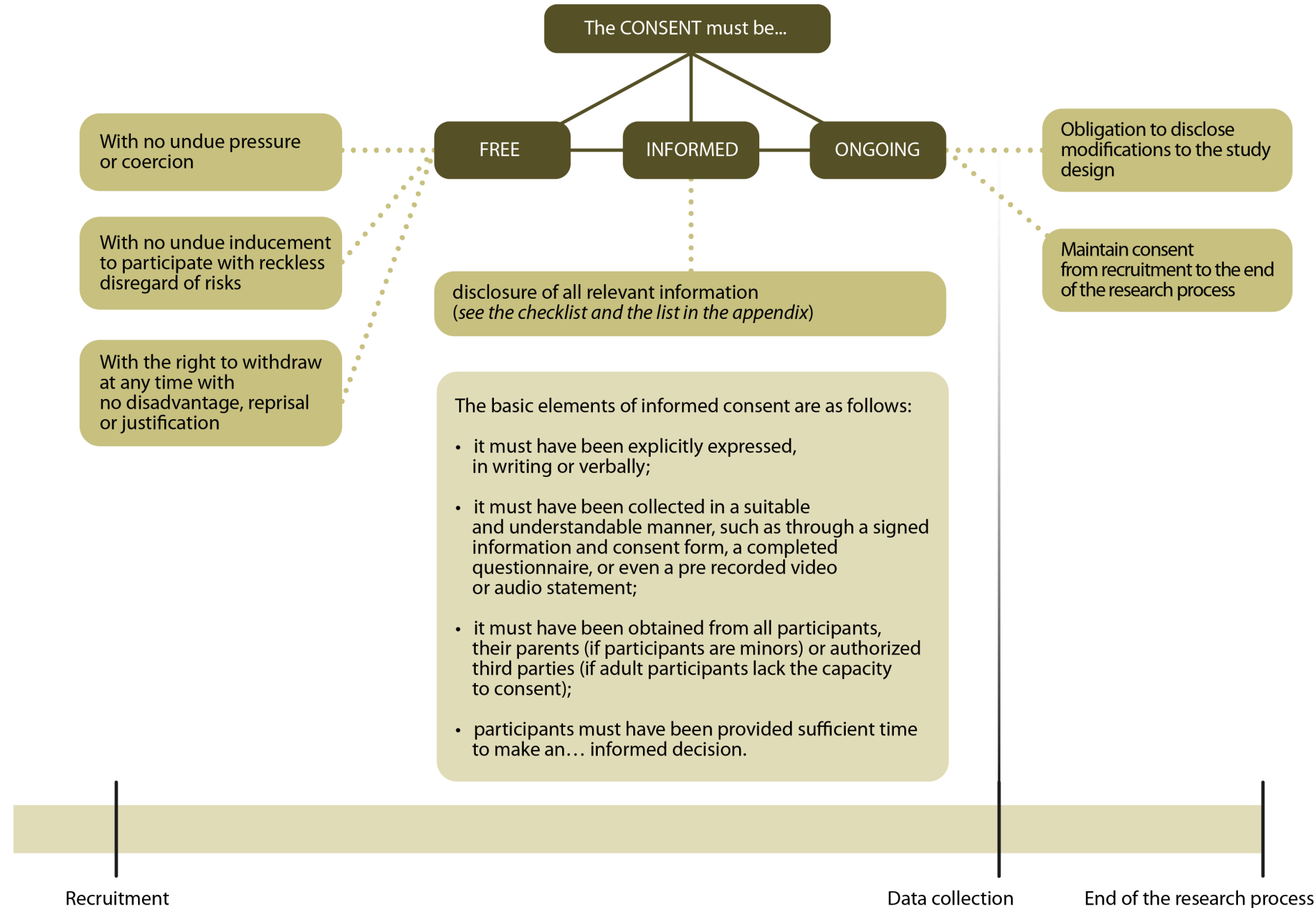
Issues

- 1 Submitting a REB application for ethical review requires skills and competencies that are typically acquired after several years of experience. At the college level, where research is not an activity carried out by all faculty members, courses *introduce* students to research; the duration of the lessons makes it difficult for students to master the concepts necessary to write and present the expected documents.
- 2 The REB may choose to delegate the ethical review of course-based research activities to non-REB members, but the latter must have the required experience, expertise and knowledge.
- 3 In cases that require an ethical review, the inherent deadlines in an education environment are very short.
- 4 Any delay in the ethical review of a research activity is likely to compromise its completion and, as such, the students' academic achievement.
- 5 The professors to whom the ethics review has been delegated may find themselves in a conflict of interest arising from their dual role.
- 6 Delegated reviews require a report to be submitted to the REB, which may increase the workload of delegated reviewers depending on the mechanisms established.

Suggestions

- 1 Allow only minimal-risk research activities.
- 2 Avoid research involving minors, vulnerable persons or adults incapable of giving informed consent.
- 3 Avoid research activities that contravene the principles of consent, such as deception.
- 4 In the case of a delegated review, ensure that the ethics review is conducted by two or more individuals with complementary skills and who have no connection with the research project.
- 5 Set up training and support for delegated evaluators.
- 6 The REB may draw up a list of pre-approved or, on the contrary, prohibited research activities.
- 7 If the research is led by a team, ensure that responsibility is shared among all members and the professor rather than placed on one particular student.

Consent



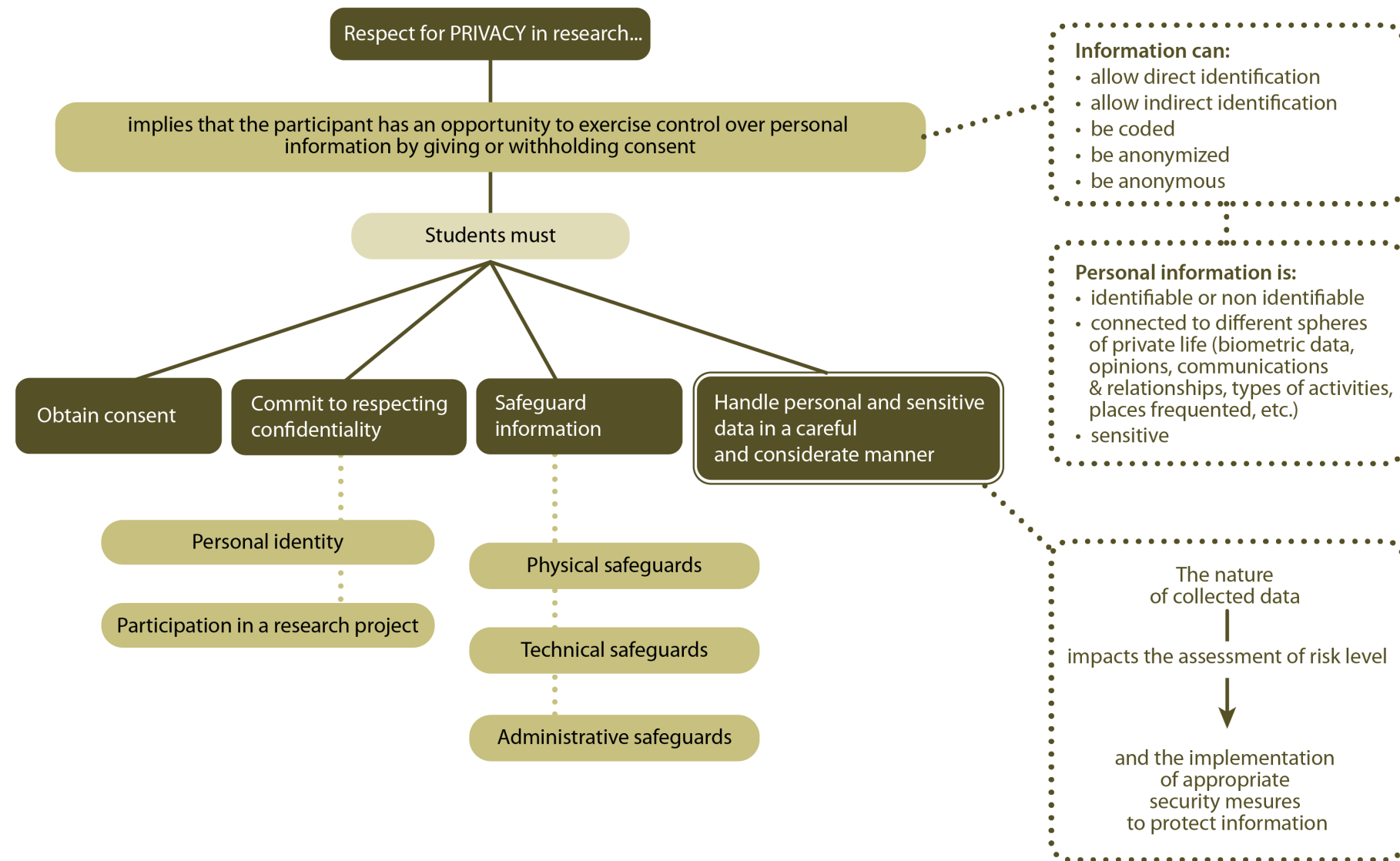
Issues

- 1 Obtaining authorization from the institution where the research will be conducted may be a prerequisite for recruiting participants.
- 2 Informed consent procedures carried out in an educational context must ensure that participants fully understand the purpose of the project, the expected procedures and duration, as well as the risks, disadvantages and benefits of their participation.
- 3 The right to withdraw consent may prove more difficult to apply in the context of pedagogical research activities.
- 4 Students who conduct research activities may find themselves in a conflict of interest, particularly when participants are recruited from within their social groups.

Suggestions

- 1 Recruit participants from outside student groups, whenever possible.
- 2 Avoid research involving minors, vulnerable persons or adults incapable of giving informed consent.
- 3 Avoid research activities that involve deception or other activities that contravene the principle of consent.
- 4 Give preference to obtaining specific consent so as to avoid re-use of data for another research activity or for secondary analyses.
- 5 Give preference to written evidence of informed consent.
- 6 Ensure compliance with applicable decision-making laws and regulations, which vary by province.
- 7 If the research is led by a team, ensure that responsibility is shared among all members and the professor rather than placed on one particular student.

Confidentiality



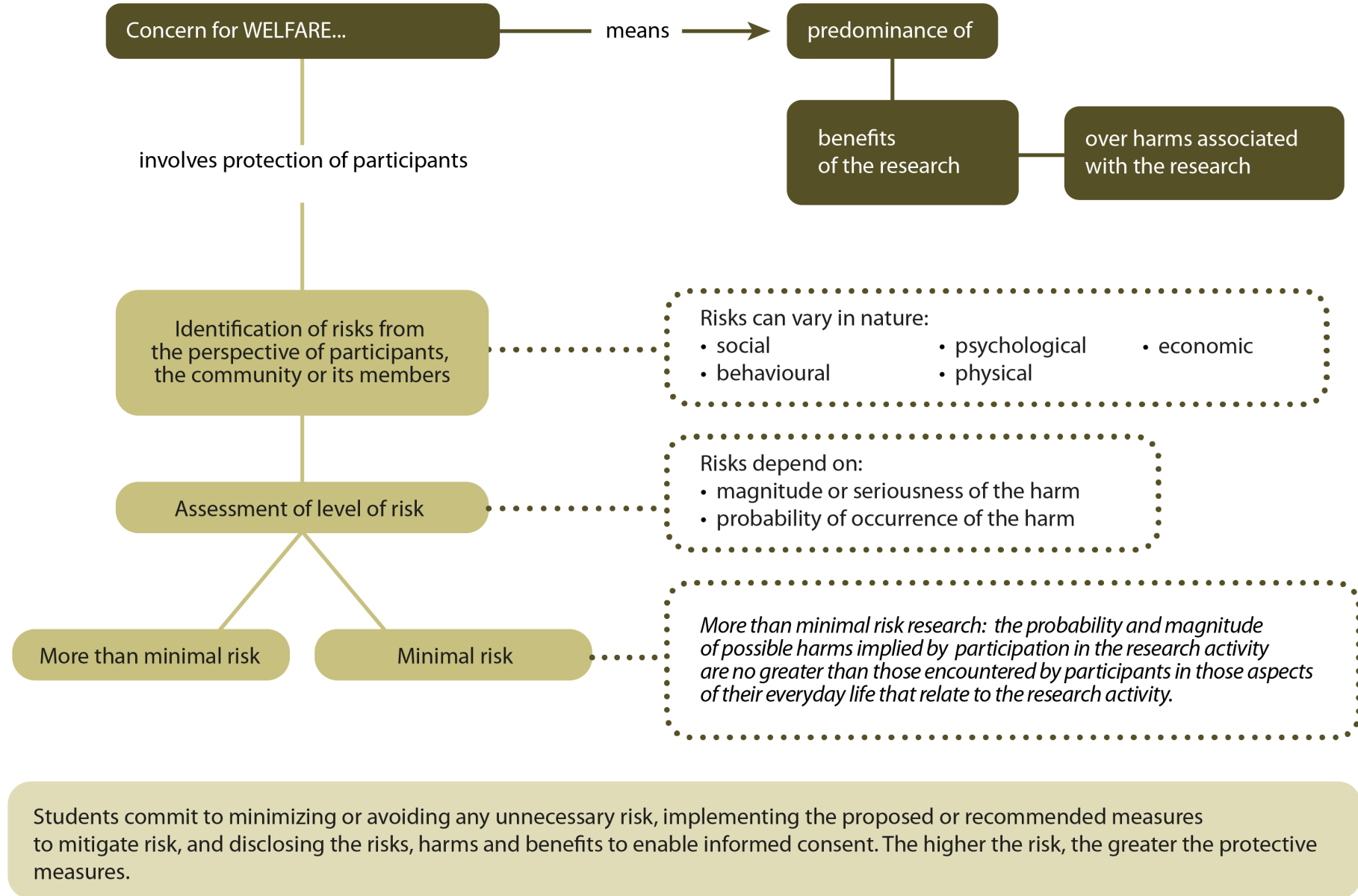
Issues

- 1 Confidentiality and privacy must be maintained throughout the research process and may continue after the research activity is completed and, as such, after the course ends.
- 2 The commitment to confidentiality and privacy should not be taken lightly, even though individuals share a great deal of personal information on a daily basis.
- 3 While digital tools facilitate the collection, processing and storage of data, they also increase exposure to the risks associated with unauthorized access to personal information and the resulting harms.
- 4 The collection and retention of personal information, even sensitive information, may be subject to specific jurisdictions such as the laws of another country, depending on the digital tools used.
- 5 The protection of research data calls for prevention and security practices and measures that are sometimes difficult to control, apply or supervise.

Suggestions

- 1 Provide a form which states a commitment to confidentiality during and after project completion, and more broadly to carry out the project in accordance with the core principles for ethical research involving humans.
- 2 Focus on using the institution's tools and data storage systems rather than private student accounts, and avoid unnecessary copies of data sets.
- 3 Avoid the use of identifying information that has high re-identification potential and instead plan for anonymized data collection or appropriate data coding mechanisms in view of the possible harms.
- 4 Limit the collection of information to only what is required by the research.
- 5 Provide a framework for data retention during the course of the project, especially if the nature of the information or the digital formats used do not allow for anonymity or data anonymization.
- 6 Establish a data destruction procedure at the end of the course or at least as soon as the grade review period has passed, and mention it at the time of consent.
- 7 If the research is led by a team, ensure that responsibility is shared among all members and the professor rather than placed on one particular student.

SCHEMA 4
Risks



Issues

- 1 Students may have difficulty identifying the potential benefits and risks associated with their research activity.
- 2 Specific skills are needed to assess risks and level of risk.
- 3 Research topics that present more than minimal risk sometimes attract attention, and this may hinder the balance between academic motivation and protection of participants.
- 4 Students may not be very familiar with the resources to which they can refer participants in order to mitigate risks resulting from a research activity.

Suggestions

- 1 Assess the risks associated with the research activity from the perspective of the participants.
- 2 Identify the risks to which participants are normally exposed on a daily basis in order to determine those that are specifically attributable to the research activity.
- 3 Allow only minimal-risk research activities.
- 4 Avoid reserved acts and take into account the rules that apply in certain fields as a result of the legal context, such as in health care.
- 5 Propose research topics or activities that present minimal risk.
- 6 Provide students with a range of resources that can assist participants who may need them.
- 7 If the research is led by a team, ensure that responsibility is shared among all members and the professor rather than placed on one particular student.

Annotated Bibliography

Student-led research activities

Achinewhu-Nworgu, E., Nworgu, Q. C., Azaiki, S. & Nna Dikeh, C. (2015). Doctoral students' understanding of legal and ethical obligations in conducting education research. *Bulgarian Comparative Education Society*, 8, 381-387. <https://eric.ed.gov/?id=ED568920>

This paper is based upon information gathered from 15 doctoral students in three inner London universities. It highlights the students' understanding of the ethical and legal issues that their research entails. The authors found that doctoral students have a clear understanding of the importance of observing their legal and ethical obligations (as stipulated in the *Data Protection Act* and the *British Educational Research Association Ethical Guidelines*), acquired through courses taken during their training. However, they recommend that more instruction and guidance be given to these students on how to apply the obligations to their particular doctoral projects, at all stages of their research. It appears that smaller-scale preliminary studies would enable them to “*learn through doing*” and to practise data privacy and anonymity, consent, right of withdrawal, and data-protection measures.

Association science et bien commun (2014). De la conduite responsable en recherche à la responsabilité sociale et environnementale des chercheurs [*Responsible conduct of research to the social and environmental responsibility of researchers*] (Thesis presented to the Fonds de recherche du Québec). https://www.scienceetbiencommun.org/sites/default/files/memoire_asbc_conduite_responsable_en_recherche.pdf

This thesis contains recommendations related to the responsible conduct of research and the social and environmental responsibility of researchers. One such recommendation proposes “support for the establishment of a basic course on research ethics for all graduate students and young researchers.” The recommendation is based, among other things, on a survey conducted by Florence Piron in 2008 regarding the ethics of science and research courses offered in Québec. Appendix 3 of the thesis provides a summary of Piron's report. The study highlights the fact that students are very interested in the ethics of science and research, and that they would actually be prepared to devote more attention to it; however, appropriate pedagogical materials are needed. The survey also highlights the key values that a course on ethics of science and research should convey for different categories of individuals, including students, instructors, directors of research or research teams, professional research staff, and lecturers.

Brey, E. M., Laas, K. & Gatchell, D. W. (2011). A Student-Centered Course for Integration of Ethics into a Biomedical Engineering Research Experience for Undergraduates. *Engineering Library Division Papers*. https://www.researchgate.net/publication/264824873_AC_2011-2272_A_STUDENT-CENTERED_COURSE_FOR_INTEGRATION_OF_ETHICS_INTO_A_BIOMEDICAL_ENGINEERING_RESEARCH_EXPERIENCE_FOR_UNDERGRADUATES

This article focuses on a 10-week summer research experience, including ethical reflection, for undergraduates in the Biomedical Engineering program at the Illinois Institute of Technology. Offered from 2006 to 2010, the experience enabled students to identify and analyze various issues in ethics and responsible conduct of research: intellectual property, conflicts of interest, the student/advisor relationship, falsification of data, etc. In questioning those who completed the course, the authors noted a marked improvement in the students' skills and critical judgement, even though they often found it difficult to describe the issue without taking sides. They recommend that this training becomes a regular course as part of the undergraduate programs, in order to enrich and broaden thinking. In the appendix, they propose cases of ethical breaches and questions to ask the students to spark discussion.

Dragon, J. & Benoît, M. (2017). La protection du sujet humain dans le passage de l'EPTC 1 à 2 : une étude de cas du recours aux données secondaires et au consentement implicite en formation clinique [The protection of human subjects in the transition from EPTC1 to 2: A case study of the use of secondary data and implied consent in clinical training]. *Revue Gouvernance*, 14(1), 43-65. <https://doi.org/10.7202/1040636ar>

This study focuses on the ethical applications of graduates in a health program offered by several universities in Ontario. These students had received professional research training and were led by university researchers. The analysis of 78 files helped identify the problems encountered in implementing the ethics rules in the *Tri-Council Policy Statement* (TCPS 1 and 2). Several breaches of ethics were observed, particularly with regard to the use of secondary data and the lack of explicit consent for such research.

Foot, H. C. (2006). Debating point: student research and ethics. *Psychology Teaching Review*, 12(1), 82-86. <https://eric.ed.gov/?id=EJ876472>

This opinion article reiterates the importance of assessing the ethics of student-led research activities to ensure that the interests and rights of participants are protected. For the author, there is no case for accepting less stringent ethical criteria just because the researcher is a student. In fact, research projects conducted by graduate students should require even more scrutiny than those led by researchers, as students are still learning. The supervisor is responsible for ensuring and even guaranteeing that the methodology chosen by the students is ethically and scientifically sound, for approving the data collection methods, and for helping them prepare their application to a Research Ethics Board. Moreover, practical course-based activities involving the collection of data from humans must also meet rigorous standards of ethics. Professors in the Psychology Department at the University of Strathclyde, Scotland, submit an application for ethics approval to the Ethics Board in which they describe the range of exercises and methodologies they will use in the classroom for teaching and assignments. This protocol, which also outlines the procedures and types of issues examined in the course, is valid for three years. This prevents students from having to fill out individual ethics review applications, which subsequently reduces the workload of Research Ethics Boards.

Hastings, A., Stockley, D., Kinderman, L. & Egan, R. (2016). Graduate student research in the classroom: Understanding the role of research ethics. *College Student Journal*, 50(3), 361-369.

This opinion piece shows that graduate and postgraduate students who are called upon to teach undergraduate students should take advantage of such opportunities, which effectively provide them with a chance to engage in the Scholarship of Teaching and Learning (SoTL) by collecting empirical data to improve their pedagogical practices and spur innovation. The SoTL has the advantage of reconciling research and teaching, two tasks that are often at odds with each other in academia. The authors conclude that students must be well versed in research ethics, and this knowledge should be acquired as soon as possible, particularly within the framework of SoTL. They recommend the CORE tutorial to facilitate better understanding of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS 2). In addition, they note that 80.3% of respondents who have completed the online training also recommend it.

Mabrouk, P. A. (2013). An Investigation of the Evolution of High School and Undergraduate Student Researchers' Understanding of Key Science Ethics Concepts. *Journal of College Science Teaching*, 43(2), 91-99. http://digital.nsta.org/publication/?i=178478&article_id=1528197&view=articleBrowser&ver=html5

This study examined the responses of American high school and undergraduate students who participated in a training program devoted to scientific research during the summers of 2010 and 2011. During a 90-minute workshop, they analyzed cases involving dilemmas in the ethical and responsible conduct of research. They were then surveyed three times to investigate their understanding of key concepts in science ethics and whether their understanding changed. Following the workshop, most of the students appeared to understand the issues relevant to data handling, but did not clearly understand laboratory safety, confidentiality, intellectual property, and authorship. Many clarified their understanding of the first two issues within two weeks of the workshop; however, understanding of intellectual property and authorship remained unresolved at the end of the training program. Based on these findings, the author concludes that a single-shot approach to science ethics training may not be adequate in providing students with the knowledge and tools they need. She suggests that discussions, case analyses, and practical exercises take place periodically during their academic training. Since 2010, all university faculty and students in the U.S. participating in NSF-sponsored and NIH-funded research must receive training in the Responsible Conduct of Research.

Munung, N. S., Tangwa, G. B., Chi, P. C, Vidal, L. & Ouwe-Missi-Oukem-Boyer, O. (2012). Are students kidding with health research ethics? The case of HIV/AIDS research in Cameroon. *BMC Medical Ethics*, 13(12). <https://bmcmethics.biomedcentral.com/articles/10.1186/1472-6939-13-12>

This study, based on an analysis of 174 research studies written from 1989 to 2010, shows that students in Cameroon who write theses/dissertations on HIV/AIDS do not take ethical issues seriously. For example, just 10% said that they had previously obtained approval from an ethics committee before collecting data from human participants. Informed consent was obtained and documented in only 48% of the theses/dissertations examined. People living with HIV/AIDS are part of a vulnerable group, and appropriate protective measures must be put in place when a researcher recruits them as participants. The authors recommend that training in human research ethics (HRE) be incorporated in the curriculum of universities in Cameroon in order to bring up the next generation of scientists equipped with a thorough knowledge and practice of these issues. Both junior and senior researchers would also benefit from continuous education and refresher courses in research ethics. In addition, universities should require students to include proof of ethics approval obtained from a Research Ethics Board when submitting their theses and other research work.

Rich, M. (2013). Everyday ethics for student research projects. *European Conference on Research Methodology for Business and Management Studies*, 327-XIII.

The author of this opinion paper finds it ironic that REBs primarily review professors' research involving human subjects rather than research activities conducted by students. In fact, committees tend to either delegate the ethics review of student course-based research activities or conduct a light-touch review, since the projects are often small scale and involve minimal risk. He suggests reversing that trend to allocate more time and attention to student-led research projects, since students are less qualified than researchers to exercise ethical judgement. After observing ethical breaches on the part of undergraduate students at the Cass Business School in London, the author reiterates the importance of teaching ethics concepts and providing the necessary support in university undergraduate programs. To this end, he recommends reviewing

(in the classroom) case studies involving ethical breaches and providing guidance throughout the development process of student-led research projects.

Richman, K.A. & Alexander, L.B. (2006). Ethics and research with undergraduates. *Ethics and Education*, 1(2), 163-175. <https://doi.org/10.1080/17449640600950782>

This article proposes a characterization of the research performed by (and with) undergraduate students in private U.S. colleges. The authors describe the context in which teaching and research are practised and the challenges that arise in terms of ethics and responsible conduct of research, in cases where students participate as "subjects" as well as "assistants." In particular, they focus on the difficulty of assessing risk and the challenges facing the Research Ethics Board of private colleges when it comes to reviewing such projects. They recommend introducing research ethics earlier in the curriculum, and in the research methodologies course.

Song, S., Choi, K. & Rhee, H. (2010). Science and engineering major students' perception of research ethics and education. *KEDI Journal of Educational Policy*, 7(1).

This article presents the results of a survey of Korean students on ethics education in science and technology. The issue of ethics is addressed in the broad sense of morality and the challenges posed by the advancement of science, scientific integrity, and the responsible conduct of research. The survey consisted of a questionnaire with three components: experience of ethics education in science and technology, opinions on ethics education, and the perception of research ethics.

St-Denis, K. (2017). Comment enseigner l'éthique professionnelle et l'éthique de la recherche [How to teach professional ethics and research ethics]. *Pédagogie collégiale*, 30(3), 9-13. <https://eduq.info/xmlui/handle/11515/37433>

In this article, the author describes an educational activity she developed in an ethics and policy course specific to the Social Sciences and Humanities program, in which she presents students with a research ethics dilemma. Since this philosophy course is usually offered at the end of the college degree, students enrolled in the Social Sciences and Humanities program have already completed the methodology courses that provide a basis for judging the scientific value of information. In fact, their academic corpus rarely offers an opportunity to address ethical principles to be respected when conducting and using scientific research. Students were asked to read the main normative codes of research ethics, then to imagine, analyze, and resolve a research ethics dilemma, during which they were to position themselves as researchers. The author reports that this approach appeared to support the development of students' professional skills and, above all, to boost their motivation and engagement in the third compulsory philosophy course.

Séguin, M. (2020). Enseigner l'éthique de la recherche qualitative en sociologie : Réflexions sur quelques dilemmes pédagogiques et déontologiques [Teaching the ethics of qualitative research in sociology: Reflections on educational and ethical dilemmas]. *Sociologie et sociétés*, 52(1), 189-211. <https://doi.org/10.7202/1076727ar>

In this article, the author shares his experience of teaching research ethics to first-year undergraduate sociology students at Université de Montréal. He explored different ways of teaching research ethics with the twofold objective of facilitating ethical reflexivity practices and ensuring that the latter helps ensure the safety of both students and participants. He opted for an experiential strategy, the core activity of his course being the gradual construction of a qualitative research project in teams of three or four. The article presents examples of

projects carried out and the ethical challenges encountered. The author concludes with four recommendations, in the form of pedagogical approaches, to promote the teaching of ethics in field research. The first recommendation is to take a professional approach to the qualitative methods training, particularly by using an experiential strategy such as that used in the research project. The second is to opt for practical rather than procedural ethics, which implies that researchers regularly assess their actions and role in the research process. In the context of a course, this involves getting students to think about and discuss various ethical dilemmas throughout their research project. The third proposes that research projects should not be reviewed by an Institutional Research Ethics Board. One reason being that the absence of an ethics certificate should increase the vigilance of students and their teachers, effectively prompting them to focus on ethics throughout the research process. The fourth and final recommendation is to encourage students to conduct surveys in a socially familiar environment, so that they are better able to judge the consequences of their presence and actions, which would help limit the risks incurred by participants.

Todorov, N. (2021). Research ethics should be taught as part of NSW higher school certificate curriculum. *Research Ethics*, 17(1), 66-72. https://www.researchgate.net/publication/341496041_Research_ethics_should_be_taught_as_part_of_the_NSW_Higher_School_Certificate_curriculum

The author of this opinion paper is convinced that the Higher School Certificate (HSC) curriculum in the state of New South Wales (NSW), Australia, should include instruction in research ethics. In fact, as part of their studies, high school graduates have to conduct a research project that requires data collection from human participants, which has the advantage of building their critical, analytic, and integrative thinking skills and of preparing them for their future roles as citizens. For Todorov, it is essential that young people understand the concepts of informed consent, right of withdrawal, confidentiality, and data anonymization. Rather than banning research on controversial topics, the author believes it is preferable to make the signing of a consent form mandatory and to include a list of available resources in cases where questions trigger distress. She also believes that teachers should be provided with guidelines for evaluating student research proposals.

Valdes, D., Jaramillo Giraldo, E., Ferrer, J. & Frey, W. Case Analysis: A Tool for Teaching Research Ethics In Science And Engineering For Graduate Students. *Engineering Library Division Papers*. <https://peer.asee.org/5729>

This paper deals with a course on ethics and responsible conduct of research offered to graduate students in science and engineering at the University of Puerto Rico. The GERESE (Graduate Education in Research Ethics for Scientists and Engineers) project includes workshops on moral deliberation and proposes analyzing cases of ethical misconduct. At the end, students give poster presentations to their colleagues on a sample case. To do so, the authors propose a moral deliberation process that includes determining facts, identifying morally problematic situations and possible courses of action; analyzing moral dilemmas and possible consequences; establishing a hierarchy of values related to morally problematic situations; and, finally, justifying the moral choices. In questioning students who had completed the training, the authors noted a marked improvement in their skills and in their moral and critical judgement.

Winder, B., Brunsten, V. & Farnsworth, B. (2007). Student research and ethics: contributing to the debate. *Psychology Teaching Review*, 13(1), 48-50. <https://eric.ed.gov/?id=EJ876477>

This opinion article reflects on what is ethically acceptable in the context of research performed by undergraduate students, while commenting on Hugh Foot's article (2006) on student research. The authors agree with Foot that there is no case for accepting less stringent ethical criteria where the researcher is a student. On the contrary, they argue that greater attention should be applied to student research projects as students

are still undergoing training. They find that their students are often attracted to 'sensational' real world research areas and, while they are loathe to restrict the students' freedoms in choosing their own research subjects, the authors stress the importance of being aware of the problems this can entail. In the Psychology Department at Nottingham Trent University, England, student research projects involving human subjects are first evaluated by the supervisor and then reviewed by the Ethics and Risk Committee (ERC). Professors also submit, to the ERC for consideration, all proposed practical work they intend to carry out as part of their courses. The ERC then delegates the review of the specifics of each student project to the professor(s).

Core texts in research ethics

Assembly of First Nations Quebec-Labrador - AFNQL (2014). *First Nations in Quebec and Labrador's Research Protocol*. <https://eduq.info/xmlui/handle/11515/38165>

This guide is used to establish rules for research activities performed with First Nations or on their territory. The protocol suggests an ethical framework for research which puts its respectful development first in a First Nations context. It highlights three fundamental values to implement a collaborative research project between a First Nations community and researchers: respect, equity, and reciprocity. This protocol is aimed mainly at First Nations who are asked to participate in research or who wish to do their own research. The scientific community is asked to consider this guide in the same way that they would for the protocols, guidelines, and other documents used in research institutions, including the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2)*.

World Medical Association (2013). WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects. <https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/>

The Declaration of Helsinki is "a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data." As the ethical standards stated ensure respect for all human subjects, it follows therefrom that the assessment of risks and benefits for participants, the drafting of a research protocol taking into account ethical issues, and the importance of Research Ethics Boards are also included in the statement. The World Medical Association (WMA) adopted the Declaration of Helsinki at its General Assembly in 1964, after recognizing the limits of the Nuremberg Code. The Declaration was then expanded and amended in Tokyo (Japan) in 1975, Venice (Italy) in 1983, Hong Kong in 1989, Somerset West (Republic of South Africa) in 1996, Edinburgh (Scotland) in 2000, Seoul (Republic of Korea) in 2008, and Fortaleza (Brazil) in 2013.

Association pour la recherche au collégial (2011). *Main normative texts on the ethics of research involving human subjects in social sciences and humanities*. http://vega.cvm.qc.ca/arc/doc/ARC_Principaux-textes-normatifs_ref.pdf

This guide presents a list of the main normative texts—recognized in Quebec, Canada, and internationally—on the ethics of research involving human subjects in social sciences and humanities. They are the standards, principles, and values that must be understood in order to improve the practice of protecting human participants when conducting research or when research projects are reviewed by ethics committees.

Bayle, F. (1950, translation). Code de Nuremberg - Extrait du jugement du TMA, Nuremberg, 1947 (trad. française). *Croix gammée contre caducée : Les expériences humaines en Allemagne pendant la Deuxième Guerre mondiale*. Neustad, Ontario : Commission scientifique des crimes de guerre. [Nuremberg Code - Extract from the judgment of the American Military Tribunal (AMT), Nuremberg, 1947. *Swastika versus Caduceus: Human experiments in Germany during World War II*. Neustad, Ontario: Scientific Commission on War Crimes]. http://www.frqs.gouv.qc.ca/documents/10191/186011/Code_Nuremberg_1947.pdf/d29861b8-30a7-456e-9a83-508f14f4e6d5

The Nuremberg Code was drafted in response to the ethical debates brought about by the discovery of Nazi atrocities in the concentration camps in the name of “medical research” and the ensuing International Military Tribunal at Nuremberg. To ensure that such horrors never happen again, the ethical principles adopted have served as a reference for drafting many of the documents on ethics in the 20th century. Thus, informed consent became absolutely essential for research involving humans, which in turn led to the following principles: participants must be at liberty to withdraw from an experiment, and researchers must be prepared to terminate the experiment at any stage in the event that it “could result in injury, disability, or death to the experimental subject.”

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1979). *Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*. https://www.hhs.gov/ohrp/sites/default/files/the-belmont-report-508c_FINAL.pdf

On April 18, 1979, the U.S. Department of Health, Education and Welfare published this document, known as the Belmont Report, in reference to the conference centre where it was drafted. The Belmont Report identifies ethical principles for anyone conducting research with human subjects: respect for persons, concern for welfare, and justice. It also indicates the areas of application of these principles: free and informed consent without deception, assessment of risks and benefits for participants, and the principle of justice, which is based on the fair selection of research participants. These principles form the basis of current practices of Research Ethics Boards (REBs). The troubling ethical breaches identified in medical experiments are what spurred the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research to establish rules for the protection of human subjects and to propose guidelines to help resolve the ethical issues associated with research.

Social Sciences and Humanities Research Council, Natural Sciences and Engineering Research Council of Canada, Canadian Institutes of Health Research (2018). *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2)*. https://ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2018.html

The TCPS 2 (2018) is a joint policy of Canada’s three federal research agencies to promote the ethical conduct of research involving humans. Informed, in part, by leading international ethics norms, it is based on the core ethical value of respect for human dignity, which requires that research involving humans be conducted in a manner that is sensitive to the inherent worth of all human beings and the respect and consideration that they are due. It serves to guide Canadian researchers in the conduct of their work involving human subjects, as well as the creation and operation of Research Ethics Boards (REBs). Articles 2.1 and 6.12 address the ethics review of course-based research activities.

Quebec Native Women Inc. (2012). *Guidelines for Research with Aboriginal Women*. https://www.faq-qnw.org/wp-content/uploads/2016/11/QNW-2012-Guidelines_for_Research.pdf

This document describes the context of research involving Aboriginal peoples in general and Aboriginal women in particular. The guidelines outline an approach that will help establish a transparent, equal, and mutually respectful relationship between the Aboriginal women and the researchers. It also presents a brief overview of existing tools and sets out a number of principles (e.g., OCAP: ownership, control, access, and possession of information) and methods (research steps and methodologies) to be applied. Lastly, it presents a checklist for use in the analysis of proposed projects and a bibliography that is intended to be both inclusive and open-ended.

Fonds québécois de la recherche sur la société et la culture (2002). *Orientation du Fonds québécois de la recherche sur la société et la culture – Éthique de la recherche sociale : consentement libre et éclairé, confidentialité et vie privée* [Quebec Research Fund-Society and Culture (2002). *Orientation of the Quebec Research Fund for Society and Culture – Ethics of Social Research: Free and Informed Consent, Confidentiality, and Privacy*]. https://frq.gouv.qc.ca/app/uploads/2021/04/orientations_frsc_consentement_confidentialite_2002.pdf

This document presents the orientations of the Fonds de recherche du Québec – Société et culture (FRQSC) regarding ethics in social research, particularly the issues of confidentiality and free and informed consent. It was developed to raise awareness in the Québec scientific community about the importance of ethical issues and to provide guidelines for Research Ethics Board members. A summary table lists the laws, mandatory standards (related to TCPS 2), and supplementary standards (FRQSC orientations) that apply to free and informed consent. This table is followed by a presentation of the rules to be taken into account, for each level, as well as excerpts from the Civil Code of Québec, the Charter of Human Rights and Freedoms, the Professional Code, etc. Mock situations in the form of thumbnails and examples of consent forms complete the document.

Fortin, M. F. & Gagnon, J. (2016). *Fondements et étapes du processus de recherche : Méthodes quantitatives et qualitatives* [Foundations and Stages of the Research Process: Quantitative and Qualitative Methods]. Chenelière éducation.

This book is a reference tool that outlines the main characteristics of the scientific research method used in the various disciplines. Chapter 9, on ethics, presents the principles and practices of good conduct when planning and conducting research. It is based in particular on the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2* (2014). As this is a pedagogical document, it includes questions for reflection and review exercises.

Hobeila, S. (2018). L'éthique de la recherche [Research ethics]. In T. Karenqué & L. Savoie-Zajc (ed.), *La recherche en éducation* (4th Ed., pp. 51-83). The Université de Montréal Press.

This reference book is an introduction to research methods in the education sector. Chapter 2, on research ethics, is an introduction to the core ethical principles that guide research involving human participants, namely respect for persons, beneficence, and justice. It also includes three examples to reflect on ethical issues in the field.

Méthot, N. et al. (2021). *Responsible and ethical conduct of college research, a guide*. La Cité, Association pour la recherche au collégial.

Also available online: <https://educ.infolu/bitstream/handle/11515/38011/Responsible-Ethical-Conduct-College-Research-guide-2021.pdf?sequence=2>

This guide comprises six sections: 1) research; 2) key points of the Agreement on the Administration of Agency Grants and Awards by Research Institutions [Natural Sciences and Engineering Research Council (NSERC), Social Sciences and Humanities Research Council (SSHRC), and Canadian Institutes of Health Research (CIHR)]; 3) responsible conduct of research; 4) ethical conduct for research involving humans; 5) other resources; and 6) a complete list of the references cited in the text. The appendices include a list of essential elements for drafting a policy on the responsible conduct of research or an ethics policy on research involving humans, as well as a glossary of the acronyms often used. The guide is accompanied by a tutorial with the same name. These tools are intended to demystify the key principles concerning college research, responsible conduct of research, and ethical research involving humans. They also aim to ensure that users—whether they be colleges, research administrators within these institutions, college researchers, or students new to research—better understand their roles and responsibilities in such matters.

United Nations, Office of the High Commissioner for Human Rights (1966). *International Covenant on Civil and Political Rights*.

<https://www.ohchr.org/en/professionalinterest/pages/ccpr.aspx>

The International Covenant on Civil and Political Rights, adopted by the United Nations General Assembly in New York on 16 December 1966, protects the fundamental rights of human beings from State interference: right to life, freedom of movement, and privacy; freedom of thought, conscience and religion; freedoms of expression; prohibition of torture, slavery, and forced labour, etc. After ratification by 35 States, including Canada, the Covenant, in principle applicable by the signatory States, entered into force on 23 March 1976. Article 7 states: “No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation.”

Payen, J.-L. (2003). Les grands principes éthiques au XXe siècle (II) : De la circulaire de Weimar à la loi Huriet [The great ethical principles of the 20th century (II): From the Weimar bulletin to Huriet’s Law]. *La Revue du praticien*, 53, 1965-1969. http://solr.gmsante.fr/RDP/2003/17/RDP_2003_17_1965.pdf

The author draws a portrait of the historical context (the medical experiments conducted by the Nazis in concentration camps) that led to the adoption of basic principles underlying the ethics of human research, namely voluntary consent, the right to withdraw from the study at any time, the principle of risk-benefit ratio, and the obligation to have research based on scientific principles (Nuremberg Code – 1947). He also identifies the various ethical concepts that have gradually emerged in international agreements (Declaration of Helsinki – 1964, Manila Declaration – 1981, Huriet Law – 1988): Research Ethics Boards, constraints/benefits ratio, privacy, data confidentiality, free and informed consent. As the author explains, from the late 1980s onwards, “a major turning point had emerged, corresponding to the transition from a purely individual-centred (moral, ethical, or spiritual) to a political-legal-centred view of ethical constraint driven by the legislator’s intervention.”

Research ethics training courses

Family Health International (FHI) (2009). *Research Ethics Training Curriculum (RETC)*. <https://www.fhi360.org/sites/all/libraries/webpages/fhi-retc2/index.html>

This training, intended for researchers and REB members, aims to help them learn about the development and philosophy of ethics and to find out how ethical principles can be applied in a practical way. It deals with the main concepts generally considered in research ethics. A section on the notion of “community participation” in the research process deepens understanding on how to apply the key principles of Respect for Persons, Concern for Welfare, and Justice. The material includes ten case studies highlighting various issues, such as the participation of minors, community participation, consent, as well as resources to further explore the notions presented (bibliography, hyperlinks, etc.). The material was developed in the United States in 2009; some adjustments to the Canadian reality may be necessary. The online training is available in two formats: “self-study” and “presenter”; a PDF document (444 p.) can also be downloaded.

Family Health International (FHI) (2005). *Research Ethics Training Curriculum for Community Representatives*. <https://www.fhi360.org/sites/default/files/webpages/RETC-CR/en/RH/Training/trainmat/ethicscurr/RETCCREn/index.html>

This training is intended for community representatives who are often called upon to collaborate on research projects on health issues. It was designed specifically to educate them about their roles and responsibilities so that they have a stronger voice before, during, and after the research process. The content covers the general principles of research ethics as well as the notion of “community involvement” and “rumors.” All materials, developed in the United States and offering various case studies, are available in English, French, Spanish, and Portuguese. It includes an annotated bibliography, suggested activities, and examples of materials to use, such as a consent form. The training is offered in two formats: “self-study” and “presenter”; the latter format provides a training outline that can be used when facilitating a group. The Help page provides estimated times and the procedure for obtaining a certificate. The material dates from 2005; however, the organization still appears to be active. A training curriculum intended for researchers is also available.

Interagency Advisory Panel on Research Ethics (2019). *The TCPS 2 Tutorial: Course on Research Ethics (CORE)*.

<https://tcps2core.ca/welcome>

This tutorial provides an introduction to TCPS 2 and can serve as basic training in research ethics. The self-paced course is a media-rich learning experience that features interactive exercises and multi-disciplinary examples. It is primarily intended for researchers and, secondly, for REB members in Canada. The tutorial consists of eight modules focusing on the guidance in TCPS 2 that is applicable to all research, regardless of discipline or methodology. Individuals who have completed the entire tutorial can receive a certificate by email. In addition, institutions that wish to be able to verify whether one of their members (e.g., students, staff, faculty) has completed the TCPS 2: CORE tutorial may request Institutional Access to the website.

Méthot, N. et al. (2021). *Responsible and ethical conduct of college research, a tutorial*. La Cité, Association pour la recherche au collégial. <https://view.genial.ly/5ecd13456e2b920db7d55e40>

This tutorial is made up of seven sections: 1) definitions of responsible conduct; 2) conflict of interest examples; 3) a list of researcher responsibilities; 4) various types of breaches of responsible conduct; 5) and 6) information regarding the inquiry or investigation to carry out in the event of an alleged breach; and 7) a list of references used. This training module is intended to be an interactive tool that each person can consult at their own pace, depending on their grasp of the concepts explored within. *Responsible and ethical conduct of college research*, a tutorial, accompanies the guide with the same name. These tools are intended to demystify the key principles concerning college research, responsible conduct of research, and ethical research involving humans. They also aim to ensure that users—whether they be colleges, research administrators within these institutions, college researchers, or students new to research—better understand their roles and responsibilities in such matters.

World Health Organization (2009-2020). *Training program and resources for the ethical evaluation of research*. <https://elearning.trree.org/>

TRREE [Training and Resources in Research Ethics Evaluation] is headed by a consortium of partners from Northern and Southern countries that provides an online training program and resources for the ethical review of health research. While access to the training modules and certificates is free, there is a fee for the *Good Clinical Practice (GCP)* module. The program, based on internationally recognized ethical principles and regulations, integrates local issues and perspectives from low- and middle-income countries, most notably from African countries. It aims to strengthen the research ethics evaluation capacities in African, European, and other participating countries. The training material, available in English, French, German, and Portuguese, is designed for all those involved in collaborative research involving humans, including physician-investigators and other researchers, students, and Research Ethics Boards. The training is divided into seven modules, whereby the first three are more general and focus on an introduction to research ethics, research ethics evaluation, and informed consent.

Santé et Services sociaux [Health and Social Services] (2005; revised 2012). *Tutorial in Research Ethics*. <https://ethique.msss.gouv.qc.ca/didacticiel/mod/page/view.php?id=20>

This tutorial provides training in the ethics of research involving humans in the field of health and social services. It was developed specifically for research ethics board (REB) members and support staff who work in the health and social services network, but can also be very useful for researchers. While it deals with national and international texts, it focuses on the normative framework that is of particular concern in the Québec context. The tutorial includes various levels of training and is designed to increase knowledge and then to validate understanding through a series of questions, scenarios, and mock protocols.

Research ethics glossaries

Social Sciences and Humanities Research Council, Natural Sciences and Engineering Research Council of Canada, Canadian Institutes of Health Research (2018). *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*. [\[https://ethics.gc.ca/eng/documents/tcps2-2018-en-interactive-final.pdf\]](https://ethics.gc.ca/eng/documents/tcps2-2018-en-interactive-final.pdf)

This joint policy of Canada's three federal research agencies contains a glossary of the terms found in the document and which are related to the ethical conduct of research involving humans.

Méthot, N. et al. (2021). *Responsible and ethical conduct of college research, a guide*. La Cité, Association pour la recherche au collégial. Also available online: <https://eduq.info/xmlui/bitstream/handle/11515/38011/Responsible-Ethical-Conduct-College-Research-guide-2021.pdf?sequence=2>

This guide contains an appendix with a glossary and a list of the main acronyms related to college research, responsible conduct of research, and ethical research involving humans.

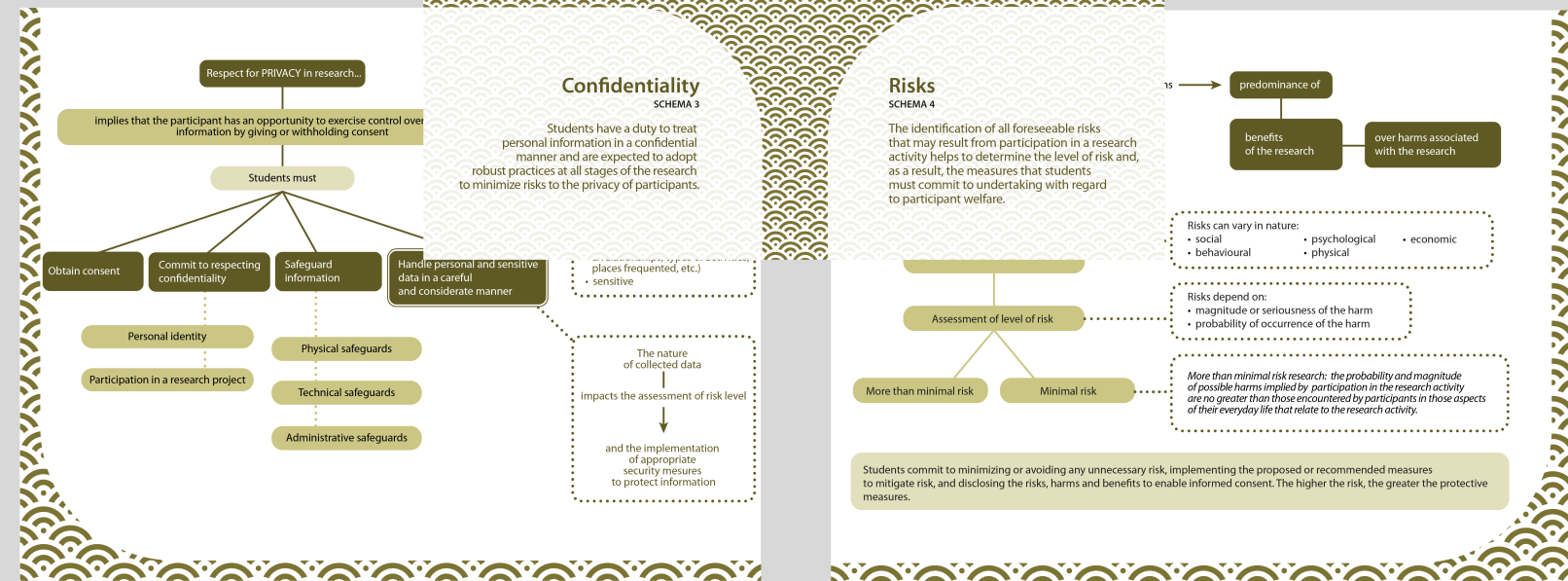
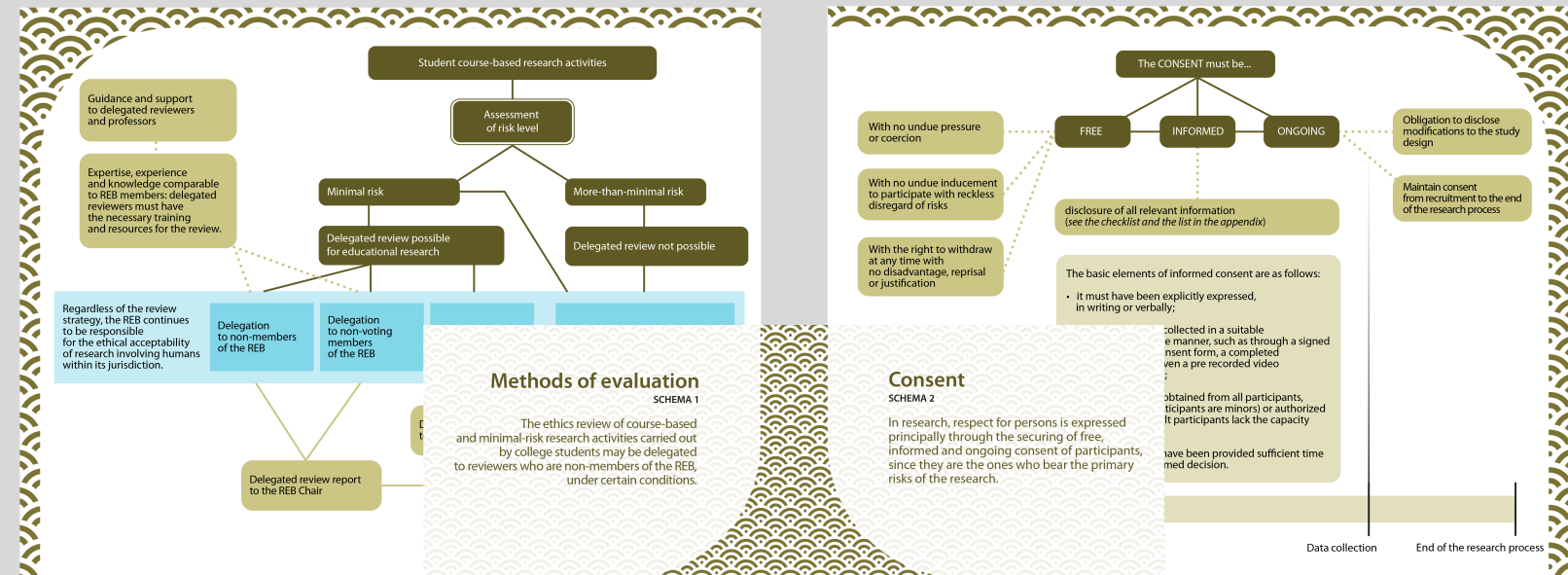
Appendix

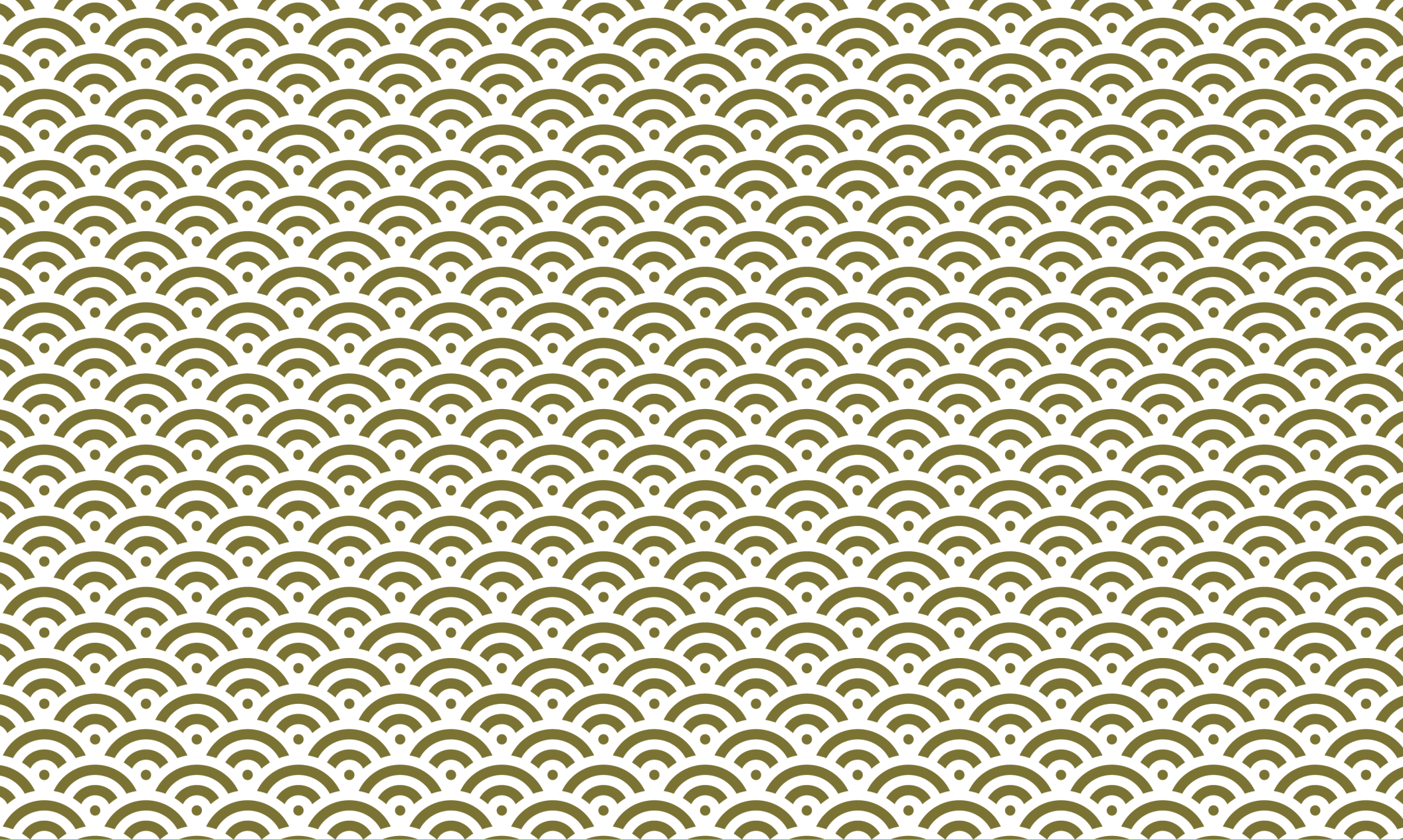
Memory aid and checklist

The following is a list of the information commonly required for informed consent under the TCPS 2 (2018). The first column of check boxes is a memory aid from which research-related information is selected; the second column is a checklist that helps ensure that all information is properly entered on the form.

- | | | | | | |
|--------------------------|--------------------------|--|--------------------------|--------------------------|--|
| <input type="checkbox"/> | <input type="checkbox"/> | A statement of the research purpose in plain language. | <input type="checkbox"/> | <input type="checkbox"/> | The identity and contact information of a qualified designated representative who can explain scientific or scholarly aspects of the research to participants. |
| <input type="checkbox"/> | <input type="checkbox"/> | The identity of the student conducting the project. | <input type="checkbox"/> | <input type="checkbox"/> | The identity and contact information of the appropriate individual(s) outside the research team whom participants may contact regarding possible ethical issues in the research. |
| <input type="checkbox"/> | <input type="checkbox"/> | The identity of the funder or sponsor. | <input type="checkbox"/> | <input type="checkbox"/> | An indication of what information will be collected about participants and for what purposes; an indication of who will have access to information collected about the identity of participants. |
| <input type="checkbox"/> | <input type="checkbox"/> | The expected duration and nature of participation. | <input type="checkbox"/> | <input type="checkbox"/> | A description of how confidentiality will be protected (Article 5.2). |
| <input type="checkbox"/> | <input type="checkbox"/> | A description of research procedures. | <input type="checkbox"/> | <input type="checkbox"/> | A description of the anticipated uses of data. |
| <input type="checkbox"/> | <input type="checkbox"/> | An explanation of the responsibilities of the participant. | <input type="checkbox"/> | <input type="checkbox"/> | Information indicating who may have a duty to disclose information collected, and to whom such disclosures could be made. |
| <input type="checkbox"/> | <input type="checkbox"/> | A plain language description of all reasonably foreseeable risks and potential benefits, both to the participants and in general, that may arise from research participation. | <input type="checkbox"/> | <input type="checkbox"/> | Information about any payments, including incentives for participants, reimbursement for participation-related expenses and compensation for damages. |
| <input type="checkbox"/> | <input type="checkbox"/> | An assurance that prospective participants: <ul style="list-style-type: none">• are under no obligation to participate and are free to withdraw at any time without prejudice to pre-existing entitlements;• will be given, in a timely manner throughout the course of the research project, information that is relevant to their decision to continue or withdraw from participation;• will be given information on their right to request the withdrawal of data or human biological materials, including any limitations on the feasibility of that withdrawal. | <input type="checkbox"/> | <input type="checkbox"/> | A statement to the effect that, by consenting, participants have not waived any rights to legal recourse in the event of research-related harm. |
| <input type="checkbox"/> | <input type="checkbox"/> | Information concerning the possibility of commercialization of research findings, and the presence of any real, potential or perceived conflicts of interest on the part of the students, their institutions or the research sponsors. | <input type="checkbox"/> | <input type="checkbox"/> | In clinical trials, information on stopping rules and when students may remove participants from trial. |
| <input type="checkbox"/> | <input type="checkbox"/> | The measures to be undertaken for dissemination of research results and whether participants will be identified directly or indirectly. | | | |

Overview





**Questions? Suggestions?
Please contact us!**

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