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Raising Awareness of Research Ethics in SoTL: The Role of Educational Developers

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Abstract

Does the subject of research ethics take you by surprise? Does it make you somewhat uncomfortable? Does it seem to have nothing to do with your research or your practice? These are the attitudes we have encountered about research ethics among some SoTL researchers at workshops and conferences. In many cases, these researchers had conducted research that should have undergone research ethics board (REB) review, but did not; that should have included a consent process for the use of student data or previous work, but did not; or that started out as program evaluation and became research without meeting the criteria of ethically acceptable research conduct. In this essay, we will argue that familiarity with our national research ethics Policy: The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2nd edition (TCPS 2) and how it applies to SoTL, is essential for researchers and for educational developers. We will propose a role for Centre of Teaching and Learning staff in raising awareness of TCPS 2 and we will dispel some of the most common myths and misconceptions that abound regarding SoTL and research ethics.

Le sujet de l'éthique de la recherche vous surprend-il? Vous rend-il quelque peu mal à l'aise? Semble-t-il ne rien avoir à faire avec votre recherche ou votre pratique? Ce sont des attitudes que nous avons rencontrées quant à l'éthique de la recherche chez certains chercheurs en ACEA dans des ateliers et des conférences. Dans de nombreux cas, les chercheurs ont effectué des recherches qui auraient dû être examinées par les conseils d'éthique en recherche, mais qui ne l'ont pas été; qui auraient dû comprendre un processus de consentement pour l'utilisation de données sur les étudiants ou de travaux antérieurs et pour lesquelles mais ils n'en ont pas, ou qui ont commencé par être une évaluation de programme et qui sont devenues une recherche sans toutefois respecter les critères relatifs à la conduite d'une recherche éthiquement acceptable. Dans cet essai, nous expliquons que la connaissance de notre politique nationale d'éthique en matière de recherche : l'Énoncé de politique des trois Conseils : Éthique de la recherche avec des êtres humains 2e édition (EPTC 2), est essentielle et nous montrons en quoi elle s'applique à l'ACEA. Nous proposons un rôle pour le personnel du Centre d'enseignement et d'apprentissage afin de mieux faire connaître l'EPTC 2 et dissipons les mythes et idées erronées les plus courants qui abondent concernant l'ACEA et l'éthique de la recherche.

The inspiration for this essay arose at recent conference where we encountered scholarship of teaching and learning (SoTL) researchers who, in our opinion, were completely unaware of research ethics guidelines that clearly applied to their work. Here, we offer two anecdotes of our experiences:

> I spoke with a number of researchers at the poster session about the 2nd edition of Tri-Council Policy Statement(TCPS2) and available educational materials – such as the online tutorial. In one conversation I had with a scholar of …, we talked about when research ethics review is necessary for SoTL research. She spoke of "just trying things out" with her students before submitting a proposal to the research ethics board. She was quite surprised to learn that "just trying things out", when it is for a research purpose, is considered to be research involving human participants by TCPS 2 – and needs to reviewed by a research ethics board (REB) beforehand.

> I went to a presentation about a new technique for student assessment. The presenter gave a brief history of the topic/issues/development of assessment strategies and immediately logged into her course management system and showed us her gradebook with all the actual students' names and marks. She then proceeded to show us again actual examples of student work. When an audience member asked about whether she had ethical clearance, she told us it was not necessary as she was not doing it for research but rather to highlight her teaching strategies for the purpose of this presentation.

Our interest in ethics awareness stems from our primary roles. Author 1 is an Educational Developer who has worked closely with her local Office of Research Services to promote awareness at her university and Author 2 is an analyst with the Secretariat on Responsible Conduct of Research. When we compared our notes from this particular conference, we were surprised to see how often ethical standards were compromised. We do not believe that the researchers in the two stories we shared above were purposely ignoring the Tri-Council Policy Statement: Ethical Conduct for Research Involving Human Participants, 2nd edition (TCPS 2). Perhaps they were not aware of it at all or they did not think the policy applied to them. The scope of this paper is to raise awareness of TCPS 2 guidance, why it applies to SoTL work, and the role of Educational Developers as champions on local campuses to promote ethical practices.

Overview of Ethics Education

In order to fully understand why a lack of awareness about ethical standards exists we need to recognize that the body of literature on research ethics is small and diverse. Aspects of this topic include: (a) governance of ethics review (Emanuel, Wendler, Killen & Grady, 2004; McDonald, 2001); (b) accounts of serious violations of human dignity and calls for more vigilant and comprehensive oversight (Schwartz, 2008); (c) analyses of the efficacy of consent forms (Flory & Emanuel, 2004; Sugarman, McCrory, Powell, Krasny, Adams, Ball, & Cassell, 1999); (d) descriptions of research ethics education on an international scale (Schuklenk & Ashcroft, 2000); (e) proposals for the improvement of research ethics education (Eisen & Parker, 2004); and (f) advocacy for a more streamlined approach (Gordon & Parsi, 2002) including the creation

of SoTL based principles for using students as participants (Hutchings, 2002, 2003; MacLean & Poole, 2010). This body of literature has been perceived as "incoherent" (Pimple, 2002). However, there are a few points about which most authors agree (e.g., De Vries, DeBruin, & Goodgame , 2004; Dubois, 2004; Eisen & Berry, 2002 ; Vallance, 2005):

- a significant proportion of researchers view ethics oversight as an obstacle to doing research and most have not been well-educated in the application of research ethics principles;
- research ethics is usually the last consideration of research design, only thought of at the time it is necessary to seek ethics review; and
- existing research ethics education is not sufficient to equip researchers with the practical skills necessary to solve ethical dilemmas in the design and conduct of their research.

In speaking with other SoTL researchers at the conference who were aware of TCPS 2, we were told they were frustrated with the research ethics process. Most did not fully understand that, by not getting REB review for their projects, they were putting their careers and their institutions at risk. The entire process was viewed as being too confusing, too time-consuming, too onerous and/or not applicable to them. We talked about how to educate SoTL researchers about why REB is necessary, when it is required, and also, how to make the process more user-friendly. We believe this is the first step on that journey.

Why is there Research Ethics Review?

The system of research ethics review exists to ensure that the autonomy and well being of research participants is respected at every stage of the research process. Research ethics review is guided by policies and/or legislation in almost every country. The universal theme of research ethics guidance is respect for human dignity. TCPS 2 expresses this theme through three core principles: (a) respect for persons, (b) concern for welfare, and (c) justice.

The concern about participants does not stem from a suspicion that researchers have ill intent, but rather from a long history of incidents in which participants suffered unnecessarily for the purposes of research. The most egregious examples have most often involved biomedical experimentation on prisoners, slaves, people with mental disabilities, and people who were never told they were part of an experiment. The Nuremberg Code, the Helsinki Declaration, the Belmont Report, and Canada's first TCPS document were motivated, in large part, by a desire to prevent unethical biomedical experimentation. It is understandable how researchers in non-medical fields of inquiry might wonder how the research ethics policies that arose to prevent similar incidents could possibly apply to their work.

Research ethics guidance may have emerged from the biomedical world but it is now recognized that there is a need to acknowledge and manage risks to participant well being that arise in social sciences, behavioural and humanities research. TCPS 2 offers guidance on these issues, such as privacy and confidentiality, conflict of interest, the consent process, pilot studies, observational studies, research with children/minors, and secondary use of data – among many others.

Does TCPS 2 Apply to You?

TCPS 2 was released in 2010 by the three federal research agencies: (a) The Canadian Institutes of Health Research (CIHR), (b) The Natural Sciences and Engineering Research Council (NSERC), and the Social Sciences and Humanities Research Council (SSHRC). The three agencies agreed to have a common research ethics policy that would govern all research eligible for agency funding. The Panel on Research Ethics, an independent group of representatives from the research community, and the Secretariat on Responsible Conduct of Research, are responsible for policy development, evolution and interpretation, as well as public outreach and education.

All institutions that wish to be eligible to apply for federal research funding are asked to sign a memorandum of understanding (MOU) with one or more of the Agencies. This MOU includes, but is not limited to, obligations to adhere to policies on research integrity, financial management of public funds, as well as TCPS 2. If an institution has signed this MOU, then researchers employed by the institution are also expected to adhere to these policies. This is because the institution is responsible for all research conducted under its auspices. This includes research conducted by anyone affiliated with the institution (students, faculty, staff, etc.) anywhere in the world – regardless of the source of funding or even if it is not funded at all.

Responsibility of the Institution and the REB

Under TCPS 2, institutions are responsible for establishing one or more research ethics boards (REBs) to review research proposals or to make arrangements to have their research reviewed by another institution's REB. If an institution is found to not be in compliance with TCPS 2, the agency(ies) can suspend their eligibility for research funding. Depending on the extent of noncompliance, this could affect individual researchers, one or more departments, and possibly the entire institution. Existing grants could be suspended and no new grants could be applied for by members of that institution.

The REB of an institution is responsible for evaluating the ethical acceptability of research conducted by anyone affiliated with the institution. The REB membership must include people with expertise in the areas of research supported by the institution, as well as an expert on research ethics, and a member of the community who is not affiliated with the institution to provide the participant perspective. The REB and its support staff are a resource for researchers. Their purpose is to help researchers address ethical issues in their research design so that the research can be done without unnecessary risks to participants.

TCPS 2 advocates a proportional approach to research ethics review, such that the level of review is in accordance with the level of risk posed by the research to participants. For example, a survey of student satisfaction with course offerings would normally be considered minimal risk (that is, not posing a risk greater than they would encounter in their daily lives) and would receive delegated review (review by one or two REB members). If the survey also included questions about sensitive topics such as sexual activity and orientation, drug and alcohol use, and/or psychiatric history, the research would likely be considered more than minimal risk and would receive full board review (involving the entire REB membership).

Regardless of the level of review, the REB members assigned to each proposal evaluate the nature of risks to the participant, how the researcher proposes to minimize or manage these

risks, and whether the benefits of the research (to the participants, to society) justify those risks. Reviewers typically work with researchers to identify ethical issues and help them come up with solutions that allow the research proceed.

The Role of Educational Developers

When researchers do not know how to apply ethical guidance to their research design this can lead to delays in ethics review, frustration on the part of researchers, and resentment towards REBs and their role within the research process. To further compound the issue on how to apply ethical practices, there is a consensus within the research ethics education literature that presenting regulations to researchers and warning them of the penalties they face for non-compliance has not yielded the desired result of establishing the integration of research ethics into research design and conduct as a professional norm (e.g., Dubois, 2004; Eisen & Berry, 2002; Eisen & Parker, 2004; Pimple 2002; Vallance, 2005).

How can we better foster a culture of research ethics? How can we ensure that new researchers are not only aware of research ethics principles but know how to apply them to research design? Given the attitude many researchers have towards the necessity of obtaining research ethics review, how can we engage them in education (Ames, Murphy, Waples, Mumford, Brown, Connelly, & Devenport, 2009)? It is our belief that Educational Developers are ideally placed to play this role, especially in work surrounding the Scholarship of Teaching and Learning (SoTL). For example, when an educator comes to an Educational Developer for advice on SoTL activities, this is an opportunity for that Developer to ensure that the educator is aware of the need for research ethics review of any research activity involving human participants (e.g., their students, their colleagues). This is their responsibility as ethical researchers as well as to the institution.

From a practical perspective, the Educational Developer can highlight the need to apply research ethics at the research design. Considering the participant perspective from the beginning will help the researcher:

1. Fine tune their inclusion and exclusion criteria;
2. Make their participant recruitment approach more successful;
3. Tailor their consent process;
4. Make their task instructions more effective; and
5. Identify any gaps in their data management strategy.

Dealing with ethical issues at the design stage can only strengthen the proposal submitted for research ethics. REB reviewers appreciate seeing ethical issues in research design dealt with practically and pro-actively. This should reduce overall time to approval as the reviewers will likely not have to ask the researcher for revisions to address these issues. It is important to urge researchers to seek advice from the REB before submitting their proposal. This will help them to identify any ethical issues that need to be addressed in advance of the submission deadlines for their research. Helping researchers and REBs build a collaborative relationship will make the review process more constructive. Educational Developers can also work with REB members and administrative staff to develop outreach and education. Well-informed researchers pro-actively applying research ethics guidance to research design will also be better able to deal with unanticipated issues and participant questions.

Myths about Research Ethics Review

Based on our research and anecdotal experiences we believe it is important to dispel the following myths about research ethics review in order for individuals to engage with the responsible conduct of ethical behaviour.

MYTH #1: Research ethics is extra work that has nothing to do with my research.

FACT: Research ethics is an integral part of research design. Research ethics principles need to be factored into each aspect of the research proposal from recruitment to dissemination and possibly beyond, if secondary use of data is part of the research plan. Addressing ethical issues requires researchers to think carefully about their recruitment strategy, their inclusion and exclusion criteria, their consent process, and instructions to participants. Taking this approach results in a better research design and a less stressful ethics review process.

MYTH #2: I'm just running the task/survey with a few people. I'll apply for REB review when I'm ready to run with a larger sample.

FACT: If you run your study on anyone other than yourself or members of your research team (e.g., for the purpose of calibrating measures), you are conducting research involving humans. Some researchers refer to this initial phase of research as a pilot study and may be under the false impression that pilot studies are exempt from REB review. To the individual participant, it does not matter if he/she is the first or the 101st person to be involved in your project. Each individual participant is entitled to know that they are involved in an ethically acceptable study, with an appropriate recruitment and consent process that has been approved by a REB,. If something happens during your pilot study that affects the welfare of any of your participants, and you did not get REB approval, the institution cannot support or defend you as they were not aware of your activities.

MYTH #3: I'm still developing my measures/questions so I'm just trying things out first.

FACT: Similar to the myth about pilot studies, "just trying things out" requires REB review and approval if it involves human participants. TCPS 2 provides for the use of emergent research design in which some aspects of the research cannot be determined beforehand but emerge out of interactions with the participants. This type of research design requires REB review and approval before any human participants can be involved.

MYTH #4: It's really just program evaluation and that's exempt from review.

FACT: TCPS 2 (Article 2.5) addresses the distinction between research requiring REB review and activities such as program evaluation (PE) and quality assurance (QA). Researchers can make this distinction by asking the question: "What is the purpose of the activity?" If the purpose of the project is to use the results of personal use (e.g., a survey of students in the instructor's class about their opinions of course materials for the purpose of improving the course), then the project is clearly PE/QA. However, if the project

addresses a research question (e.g., Do students' opinions of course materials vary as a function of teaching approach (or other factors)?) then a REB review is required.

When embarking on a PE/QA project, it is important for researchers to ask, "Could this project become research?" Often, PE/QA projects yield interesting data which can be used to address one or more research questions. If the project did not go through REB review, the data cannot be used without applying for ethics review for secondary use of data. At this time, the approach for collecting data will be scrutinized. If the project has the potential to become research it makes sense to get REB review right from the beginning.

MYTH #5: I'm working with computers/old test papers/my class notes – so it's not research involving humans.

FACT: If a researcher is evaluating aspects of a machine or device or approach that is used by human beings, it is likely that humans will be involved in the measurements and evaluations. If the research question is about the experience of humans (e.g., reactions, performance, evaluation) rather than an objective measure of functionality (e.g., processing speed), then REB review will likely be required. If the research involves previously collected data, referred to as secondary use of data for research purposes, and unless this data has never had any identifying information associated with it (TCPS 2 Article 2.4), the project will require REB review to address consent issues and privacy concerns. Similarly, the use of tests, assignments or class notes from a course carries with it risks to the privacy and confidentiality of the students associated with these materials. TCPS 2 Articles 5.5 and 5.6 discuss research involving secondary use of data and your options for dealing with consent and privacy issues.

MYTH #6: The REB is just looking for ways to block my research.

FACT: REBs very rarely deny approval to research proposals. They may ask for revisions to ensure that the research is in accordance with ethical principles. The goal of the REB is to help researchers ensure that their project is designed and conducted in accordance with the three core principles of TCPS 2 (i.e., respect for persons, concern for welfare, and justice). The more researchers know about how to apply this guidance, the easier REB review will become.

Consequences of Ignoring Research Ethics

In this paper we have expounded on the benefits of applying research ethics principles and getting REB review but it is important to remember that there are also consequences for not doing so:

- Many journals will not publish research that has not been approved by a research ethics board.
- If something happens during your study that affects participant welfare, you do not have the sanction or protection of your institution.

- A violation of research ethics may negatively affect your eligibility for access to participant pools, grants and promotion or tenure.
- Participants may lodge a complaint against you with your institution, and depending upon the severity of the situation, with the local authorities. <u>If you are accused of conducting a study without REB approval, this may damage your reputation, as well as the reputation of the institution, and of your fellow researchers.</u>

Recommendations

We recommend that educational developers champion research ethics at their institutions by working with REBs and research ethics offices to develop education for students and faculty, and by incorporating a discussion of research ethics into their individual consultations with faculty and departments. We also recommend the use of existing publicly available research ethics education resources offered by PRE and SRCR. For those new to research ethics, there is an interactive online tutorial (see TCPS 2: Course on Research Ethics (CORE) / EPTC 2: Formation en Éthique de la Recherche (FER)). This tutorial consists of eight modules that take an applied approach to the guidance in TCPS 2 featuring media excerpts, interactive exercises, and examples from a wide variety of research disciplines. For more in-depth discussions about specific research ethics topics, there is a series of webinars offered by SRCR. Recordings of each webinar are available on the PRE website for online viewing. Workshop materials and case studies are available upon request. If you have a question about how to apply any TCPS 2 guidance, you can request an interpretation from SRCR by email.

It is our hope that educational developers will take up this challenge; reach out to individual researchers and to their research ethics boards to foster a shared engagement in research ethics education.

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