A reflection on research ethics and citizen science

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Abstract
Ethics review of research involving humans has become something of an institution in recent years. It is intended to protect participants from harm and, to that end, follows rigorous standards. Given recent changes in research methodologies utilized in medical research, it may be that ethics review for some kinds of studies needs to be reexamined. The purpose of this paper is to stimulate dialogue regarding the kind of review required for citizen science-based research. We describe a case study of a proposal submitted to our research ethics board and propose different approaches to proportionate review in research involving citizen scientists. In particular, we describe how problems with the term “participant” led to confusion in review of this study and examine the study in light of current Canadian guidelines. We suggest that the term participant and indeed the general approach to low-risk community-based studies such as the one described warrant reexamination.

Keywords
Ethics review, citizen science, proportionate review, radon research

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Introduction

Research ethics review has become an integral component of medical and social science research. Almost every postsecondary institution supports at least one research ethics board (REB), also called research ethics committee (REC) or institutional review board (IRB), and larger institutions may have multiple boards serving different areas of research (e.g. biomedical, social sciences). In Canada, guidance for ethics review is provided by the Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans (TCPS2) (Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, & Social Sciences and Humanities Research Council of Canada, 2014) and other regulatory or statutory requirements (e.g. privacy legislation). The ostensible purpose of ethics review is to protect those being studied from harm, whether they be individuals, groups, or communities. The central principles on which the TCPS2 is based are “respect for persons,” “concern for welfare,” and “justice.” The policy provides considerable explanatory details to help REBs understand how these principles should be interpreted and harm mitigated. It also states that the degree of scrutiny should be directly related (proportional) to the risk inherent in the research (Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, & Social Sciences and Humanities Research Council of Canada, 2014). However, subjectivity is inherent in assessing the degree of potential harm and level of review required, which makes consistent application of standards challenging. There is also a degree of latitude in interpreting the principles. Further adding to these challenges is the fact that, with evolving methods and shifts in ontological and epistemological perspectives, what (or perhaps more accurately, who) constitutes a research “participant,” and whether, and to what degree, such a participant needs to be protected from harm, is becoming less clear. The result is that, on occasion, current approaches to research ethics review may add very little, if any, value in terms of participant protection.

Our aim is to raise some questions about ethics review in view of changes that are occurring in science and ethics understandings. For example, how do we decide what needs review? How should we consider emerging community-based approaches to research in the context of current understandings of risk and benefit? How far do the obligations of the REB go, and are there other processes or bodies that could and should instead have oversight responsibility? To accomplish this, we present a brief history of the development of research ethics standards, then outline a case study of an application that caused us to reconsider some “taken-for-granted” processes that had become our way of operating as a REB. Our purpose in presenting this case study is to illustrate the point that new ways of thinking may be required of REBs as approaches to science evolve, particularly in the context of citizen science–based research. We will dissect some of the issues
that arose in the review of this application and explore some ways of approaching these studies to ensure compliance with current ethical standards.

**Historical background**

In North America, the push for establishing an ethics review process followed revelations about egregious infringements of human rights in the context of research. In 1966, Beecher’s widely read article outlined numerous instances in which the health of patients was put in jeopardy in the interests of advancing medical science (Beecher, 1966) and in 1972, the notorious Tuskegee syphilis study was exposed and halted. In that 40-year study, poor, largely uneducated African American men in Alabama had been denied treatment for syphilis to enable researchers to follow the natural course of the disease. Participants in the study had been led to believe that they were receiving the best available treatment (Lederman, 2016). This revelation was followed two years later by the passing of the National Research Act in the USA, which legislated human subjects research regulation. Early discussions of research ethics centered largely on the four bioethical principles of beneficence, nonmaleficence, autonomy, and justice that had been developed in Georgetown, Washington, as a framework for medical practice (Holm, 2002).

In Canada, work began in the late 1980s on the first *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS), which was released in 1998. This document was developed by a group of researchers and scholars from medicine, social sciences, and natural sciences, and was intended to provide guidance for all research involving study of humans. Release of the TCPS spawned considerable criticism from researchers, particularly those in the social sciences, many of whom expressed the view that the kinds of vulnerabilities of participants in medical research are simply not present in the vast majority of social science projects (Haggerty, 2004; van den Hoonaard, 2001). They maintained that the language of medical ethics was pervasive in research ethics documents, thus shaping understandings of social science research and leading to unnecessary and unreasonable constraint of social science and social scientists (Katz, 2013).

Debates arose about terminology. For example, the term “subjects,” widely used in medical research, was felt to be inappropriate, as it denoted that those being studied were being “done to,” whereas in social science research the approach was more one of “doing with” (Gontcharov, 2011). Emerging methodologies and a growing interest in qualitative methods led to similar concerns being raised among medical researchers. The language within TCPS2 moved from “subject” to “participant,” but this raised different concerns (Gontcharov, 2011). Some argued that the word participant could include those who are conducting the study. The title of the TCPS2, *Ethical Conduct for Research Involving Humans* serves to make the issue even more obscure, as clearly all research involves humans
Research Ethics 15(3-4) (Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, & Social Sciences and Humanities Research Council of Canada, 2014). This is important because the term subject, as used in medical research, suggests an inherent vulnerability insofar as it implies a power differential. The term participant does not necessarily convey the same vulnerability, which is one reason that it is used in social science. Many community-based methodologies refer to participants as “coresearchers,” which begs the question of whether they require “protection” from an ethics board at all.

Case study: The Southern Alberta citizen scientist radon testing survey

A case in point can be found in an evolving methodology, termed “citizen science” (CS) which confounds standard thinking about ethics review. Studies using this methodology have been fairly common in botany, zoology, and the environmental sciences, but are just beginning to appear in health research (Follett and Strezov, 2015). A lack of clarity around the meaning and implications of the term participant in CS can be problematic for REBs, as we shall demonstrate. CS has been variously defined, but for the purposes of this paper is understood as “the process whereby citizens are involved in science as researchers” (Conrad and Hilchey, 2011). A CS study was submitted for ethics review to our institution’s medical REB and was subsequently approved, but not without considerable debate about whether or not its review was within the REB’s mandate and, subsequently, whether standard questions during the application were suited for CS-based studies.

The study in question, led by this paper’s coauthor AG is ongoing as of the time we write this article and is known within the public domain as the Evict Radon initiative. It encompasses an active and evolving set of CS and more traditional research projects. Radon gas is a radioactive and cancer-causing agent that is, globally, the second leading cause of lung cancer and the greatest source of life-time ionizing radiation exposure for the general population (Goodarzi et al., 2016; Zeeb and Shannoun, 2009). Early pilot initiatives involving cancer researchers and clinicians testing their own properties for radon revealed the potential impact of a CS-based approach to understanding the scale of radon exposure within a region. Media reports of the pilot test led to an enthusiasm among community members in the study area for conducting radon testing using their own resources and contributing their de-identified data to researchers.

Radiation biologists therefore conceived a study to understand how household radon gas concentrations related to specific building metrics such as home build year, size, and foundation type (and more), with a view toward understanding (a) the magnitude and distribution of indoor air radon concentrations in homes within the study region and (b) whether there were any variables that were modifiable and thus of interest in future radiation protection and cancer prevention strategies.
Citizen scientists would purchase controlled, national standard radon tests “at cost” for a testing process performed in collaboration with radon testing professionals certified by the Canadian National Radon Proficiency Program (C-NRPP), who were contracted and/or willingly volunteered their professional time. Researchers and C-NRPP professionals would oversee quality control and ensure that all radon readings and home metrics contributed by citizen scientists were appropriately collected, analyzed, stored, and de-identified such that data would be secure and no individuals or their specific home addresses would be identifiable within published datasets. Citizen scientists were advised on an electronic consent form that this would be the case.

The first phase of this study was initiated in late 2013 and results from the 2013–2016 period were published in March of 2017 (Stanley et al., 2017). During the active phase of the project, only the citizen scientists had direct access to their own radon data and test devices; the researchers received de-identified, aggregate datasets about radon levels from the central laboratory reading test devices. While researchers did not endorse any specific commercial entity for radon testing generally, to manage the testing process in concordance with national standards it was necessary for specific private companies to partner with the researchers. Citizen scientists bore the cost of their individual radon-testing kits; no profits were realized by the researchers and no data were shared further. The peer-reviewed outcomes of the first phase of this research were published in an open access journal (Stanley et al., 2017) and at public events, so that there was ample opportunity for the citizen scientists to see the results of their efforts. Published findings were also open to the broader public and policy makers. The study is now in a second phase with a distinct study region and remains open with the same general mandate and risk considerations.

The first phase of the project was viewed as an academic success with implications in terms of knowledge translation (Stanley et al., 2017). Indeed, it led to a substantial increase in public knowledge about radon hazards within the province of Alberta and formed the essential rationale for legislative action, in the form of the first ever Radon Testing and Awareness Act (Bill 209) that was passed within the provincial legislature within 10 months of the study’s publication. However, the study raised some issues with respect to the appropriateness and proportionality of ethics review.

**REB considerations**

At the outset the researchers contacted the REB requesting a consultation to determine whether or not ethics review was required. The project was considered, and it was determined that the participants would be acting as citizen scientists, contributing data about their home metrics such as radon levels, environmental design features, and furnace type. The role mostly closely aligned with that of a research assistant or team member. Their motivation was assumed to be their desire to
contribute to the understanding of a potential risk factor (i.e. radon exposure), an issue of importance to the broader community. While it was acknowledged that the study most certainly involved humans, their involvement as participants in the sense of research subjects in need of protection was thought not to apply. Moreover, the nature of the project involved reporting nonhuman data to researchers together with an industry partner in a manner and at a cost consistent with how the industry conducted its usual business. The research project team ultimately de-identified all human data collected as a necessary part of the study process, such as e-mail addresses and names, and only released radon and home metric results in a broad, aggregate manner where even modestly identifying regions (such as neighborhoods) could not be isolated. The REB exempted the project from the need for research ethics review, considering it not to be human subject research. The study was launched and, within less than one week, >2000 people had been recruited through an opt-in consent process at the study’s main website that routed into the industry partner’s secure webstore to obtain radon test kits “at cost” for the specific purpose of the study. Citizen scientists learned about the study via traditional media coverage of the research, communication via partner organizations (e.g. Canadian Cancer Society, Lung Associations), and social media advertising.

Within a week of launching, a letter was received by the REB outlining several concerns with the study, including the lack of ethics oversight, the consent, need to purchase the radon test kit, and possible conflicts of interest. The complaint was made by an individual who had served on a REB and had an academic interest in issues relating to institutional reputation. In light of the concerns raised, the REB requested that the investigators halt the study and the need for review was revisited by the REB, the researchers, and the institution.

Second-guessing and revisiting requirements

While recognizing that the citizen scientists more closely resembled research assistants than typical research subjects, the REB noted that engaging the public through an invitation to take part could be construed as consistent with study recruitment activities. Moreover, review of the project materials revealed a lack of clarity about the relationship of both the institution and the research team to the radon-testing company, as well as some areas where the consent did not fully meet research ethics norms and standards. Erring on the side of caution, the REB chose to undertake a post hoc delegated review, although there remained considerable debate about whether this review was within the REB’s mandate or whether another institutional body, such as the legal department or communications office, would have been better placed to review.

Applying the core principles of the TCPS2 (respect for persons, concern for welfare, and justice) (Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, & Social Sciences and Humanities
Research Council of Canada, 2014) yielded the following analysis: On the first principle, as previously noted, the review process for this project was challenged by the blurry definition of participant. Generally speaking, “research participant” is understood to mean an individual or group under study. Clearly the citizen scientists who opted in and responded to recruitment materials were participants in the study, but were they participants in the sense of being studied as such? Citizen scientists performed data collection and willingly contributed time and resources to answer a question in which they had great vested interest. They reported specific scientific data about their homes, but at no time were asked to provide personal information such as psychosocial or health metrics beyond basic contact information (name, e-mail, postal address). The units of study were the properties, not the people. The study had been fully explained to the citizen scientists and they had signed a form that explicated use and protection of data and promised confidentiality. It was more like a contract than a consent form but did include most elements of a consent commonly required by REBs.

In consideration of concern for welfare, the review revealed that information being collected was not personally sensitive or stigmatizing. Direct benefits accruing to the citizen scientists as a function of study involvement were a $5.00 reduction in the cost of the test kit and the satisfaction of contributing to the scientific body of knowledge. Radon test results and information on radiation remediation were not considered to be direct study benefits as they would accrue to anyone choosing to purchase the commercially available kits and test their homes for radon but not participate in the study. Data security and privacy protections met institutional standards such that a breach or inadvertent disclosure, though possible, was highly unlikely. Possible harm included upset at finding out a home had unsafe levels of radon, but as above, this was not research related. Citizen scientists did not have to be part of this study to choose to examine radon levels in their home. Given the degree of interest in the question due to established high radon gas geological potentials for the area (Stanley et al., 2017) and the documented incidences of radon-related disease (Grundy et al., 2016), this seemed a risk no greater than risks of everyday life and stood to confer a possible benefit.

Justice considerations centered on access to the test kit and study for all those interested. Although there was a minimal cost for the radon-testing kit, it was $5.00 lower than would normally be the case. This modest amount was judged unlikely to influence an individual’s ability to participate. Only those who had a direct personal interest in determining radon levels in their homes were likely to purchase the kit and anyone in the study area was free to participate.

The conflict of interest concern raised related to the perceived association of the institution with the test company as the institution’s brand appeared on the company’s site with the study link. Acknowledging the potential for misinterpretation, the REB in consultation with legal services recommended that recruitment be limited to the university researcher’s website alone and the university logo be removed from
the industry partner’s website. Explicit statements about the financial independence of the research team from industry partners, or indeed any aspect of for-profit radon industry, were also added to the consent and recruitment materials made, together with a plain-language explanation of the need to engage with certified industry professionals to meet national regulatory standards for radon testing.

In summary, reviewing the project from a research ethics lens did not afford those choosing to participate any measurable additional protections. Concerns of potential importance to the institution from a public relations perspective related to citizen engagement and the impression that the institution could be seen to be endorsing the services of the specific radon-testing company. Removing explicit associations between the institution and the company addressed this concern.

**Moving forward: recommendations for REBs**

We concluded that the issues encountered during this case study were of evolving standards and difficulties in interpreting existing policy with respect to what constitutes “research with humans.” In an era where those who would formerly have been considered subjects are increasingly becoming partners in the research enterprise, the question needs to be examined more closely. Arguments from social scientists around overly restrictive interpretations and resultant constraints on research seemed to ring true in this instance. Extending the argument, one might turn to research programs where former patients are trained to engage in data collection. Should they be considered participants or coresearchers? Do they require ethics protection?

The TCPS2 was developed to protect individuals under study from unnecessary risk and to ensure that mechanisms would be in place to ensure full understanding of risks that subjects would assume. The need to broaden terminology to make it more consistent with current standards resulted in the change from “human subject” to “human participant” to “human,” leaving it ambiguous and difficult to interpret. Application of rigid approaches to review based on old understandings of “subject” seems unproductive if the intent is to protect from harm. One must ask what harm is prevented when there is very little risk to individuals in a particular study design. The TCPS2 advocates “proportionate review” but does not really make space for studies such as those described in the case study mentioned. Citizen scientists are not study subjects as such and requiring a research ethics review seems unjustified. A newer approach must be considered. This position is consistent with the recent changes to the Common Rule in the USA, where an expanded list of studies exempt from review has been released (Protections, 2016).

It is important to recognize that we are not advocating for no oversight of such studies. What might be questioned is which body within the institution should undertake this responsibility. The institution’s response to concerns that were raised suggested that perhaps the issue was one more properly situated with the legal department or communications/public relations. The process undertaken in
at the inception of this study seems logical: An individual versed in ethics principles and process looked at the study and made a determination as to whether it entailed risk and needed to undergo full ethics review. The decision was made that it did not, but outside perceptions suggested that participants were not being properly protected. Where the challenge arose was in the ambiguity in definition and understanding of human participants leading us to reexamine our original decision. Considering citizen scientists as research assistants seems to mitigate these concerns, but before this approach can be embraced it must be debated more fully.

Conclusion

Our intent in this article was to illuminate an issue, stimulate discussion, and provide some direction for resolution of similar concerns in future. Similar arguments about other evolving methodologies will need to be made as understandings develop. A continuing dialogue is important to prevent a hegemonic application of “ethics rules” that fail to meet the mandate of ethics review: prevention of harm (Robson and Maier, 2018). In the case study described here, it could be argued that harm was created by arousing unnecessary anxiety among reviewers and researchers alike. During the time that the study described earlier was on “hold,” many potential citizen scientists contacted the researchers, hoping to be a part of the research. Denying them access raised anxiety among community members who wanted to be part of expanding knowledge on this very important topic. It seems that instead of protecting participants, outmoded rules regarding ethics review were potentially doing just the opposite. We urge readers to continue the dialogue with the aim of ensuring that research ethics review processes are as positive and supportive of all participants as possible.

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