Ethics Amendment*

Articulating epidemiological data harmonization initiatives as practical and collaborative experiences

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Please describe the proposed study amendment or modification and the rationale. Is it Minor (e.g., administrative changes, change in sponsorship/study funding) or Major (e.g., adding an intervention such as additional blood tests, or changes to the study design, changes to the study population)?

The overall research questions and methods remain the same. However, as I made preparations to initiate data collection, it became clear that I needed to shift to a single case study approach. This is due to several practical and epistemic limitations and opportunities, outlined here.

I came to realize that the community stakeholders that I relied on to gain a better initial understanding of the topic of interest (data-sharing), and who I have been consulting to help identify potential cases, represent only a small component of the topic of interest. Specifically, I was drawing very heavily on the field of data harmonization, which is one aspect of data-sharing. I therefore became aware of a strong bias in my sampling strategy that I now seek to rectify.

Moreover, the research centre that hosts some of these stakeholders, and which employs several potential study participants, has recently been struck with a sustainability crisis due to lack of continued funding. On an interpersonal level, it would be insensitive of me to ask people affected by these cuts about the field that they may no longer be able to participate in. And more importantly, on a scientific basis, if I were to proceed to interview these affected people, their responses would undoubtedly be biased based on these recent developments, in ways that are not possible to control for and that are not conducive to the study's objectives. Leaning in to and leveraging this recent development is also not an option since this would steer the study too far away from its objective and mandate.

At the same time, I already have access to one well-rounded case: the CITF Databank. Through this case, I will be able to touch on many aspects of the study's objectives. Moreover,

*This is an automatically generated PDF. Refer to the project website for continuous updates at https://zackbatist.info/CITF-Postdoc.

under a single case study method, all prospective participants share a common frame of reference, whereas the diversity of contexts under a multiple case study approach makes it more difficult to find common ground that supports a basis for rigorous comparison. In terms of practical affordances, this study was initiated by the CITF Databank with an understanding that I would be investigating their research practices. As such, I have already been granted access to the CITF Databank as a case and I am able to access key personnel as prospective study participants.

One implication of this change is that it will be more difficult to maintain confidentiality. Since the study is based on a single case, and my involvement with the CITF Databank is common knowledge, it would be relatively easy to conclude that the CITF Databank is the case even if its identity was obfuscated in data records and documentary materials. By extension, the fact that the identity of the case is widely known makes it difficult to obscure certain people's identities, especially those who hold unique roles in the CITF Databank.

However, I do not think that it is necessary to enact a policy of maintaining strict confidentiality for all participants' responses. It has already been established that risk of reputational harm is very minimal. For the most part, participants will be asked to discuss work practices and professional relationships. The vast majority of responses are expected to be quite benign, though there is some slight possibility that participants may share something that they would not want to be publicly associated with saying. In other words, the situations when the risk to reputational harm is slightly elevated are rare, exceptional, and bounded instances, and are easy to identify and mitigate. It is therefore feasible to render those specific instances as confidential without necessarily imposing unnecessary and impractical challenges for the vast majority of information I collect.

I am committed to working with study participants by providing them with opportunities to shield their identities in public presentations of the findings when the risk is more clearly apparent. My close involvement with the case is an asset in this regard, since I am able to engage in frank and open discussion with my colleagues, and to work with them to determine what they are each comfortable with sharing publicly. This aligns with the study's emphasis on co-constituting knowledge about epidemiological research practices and value regimes through collaboration with the participants whose work will be examined. Moreover, when reviewing the data during analytical phases of work, if I sense that there may be heightened risk to reputational harm, I will approach the potentially affected participants and invite their input on how to proceed. Alternatively, I may take action to shield the individuals' identities independently of their added input. I will determine when it is appropriate to reach out to potentially affected participants based on my training and years of experience involving work with human research subjects, my consistent application of reflexive note-taking techniques, my sense of service to the community that the research is meant to support, and my understanding of my colleagues' needs and desires, as informed by clear and frank discussion pertaining to the study they will have consented to participate in.

I have modified the informed consent document that I will distribute to prospective participants to reflect these changes. I have also removed the recruitment letters for cases and individual

participants, since the leader of the CITF Databank has already agreed to have his project serve as the only case, and since I will be approaching individual participants via channels of communication that are already open to me.

Three prospective participants from the CITF Databank have already signed informed consent documents but have not yet participated in interviews; I will distribute new consent documents to them and explain what has changed. I have conducted one interview with a participant who is not a member of the CITF Databank and whose responses will therefore be excluded from the study; I will inform this participant about the decision to exclude them from the study, if it is deemed necessary.

I have made one additional modification to the ethics protocol that is unrelated to this methodological pivot. Specifically, I removed the restriction against recording online interviews using cloud-based services that are already approved by the Cloud Directive, since their approval indicates that all their functionality (including cloud-based recording features) complies with McGill's ethical data governance standards.

The modifications proposed in this amendment are the result of practical challenges emerging from a relatively minor methodological shift. I believe they strike an optimal balance between enabling scientifically sound research and respecting the autonomy and personal dignity of study participants. I welcome any additional feedback you might provide so that I may conduct this study in accordance with the highest ethical standards.

What follow-up action do you recommend for study participants who are already enrolled in the study?

- ☒ Inform study participants ASAP
- ☐ No action required
- ☐ Other (please describe)
- ☒ Revise the consent/assent forms

Please attach revised study documents, including consent form, study instruments, or study protocol, if applicable.