Ethics Protocol*

Articulating epidemiological data harmonization initiatives as practical and collaborative experiences

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Project Title: Articulating epidemiological data harmonization initiatives as practical and collaborative experiences
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Recruitment and consent

Will this study involve recruitment of human study participants?

- ☒ Yes
- ☐ No

How are potential study participants identified and/or recruited to the study? Explain how potential participants are identified or introduced to the study, and who will recruit participants. Will the investigator/s require any special permissions or access to the target population e.g. clinic access, patient registries or records, mailing lists, community access?

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

Through consultation with key community stakeholders, the principal investigator will devise a list of prospective projects to serve as cases.[1] The principal investigator will then write to the leaders of these projects inviting them to participate in the study. These invitations to project leaders will explain the project's purpose and scope, and will encourage the recipient to reply with any questions or concerns they may have. If they accept the invitation, the principal investigator will then work with project leaders to devise a list of individuals who may serve as interview candidates based on their roles in the project. The principal investigator will be clear with project leaders that they should not pressure those who work for them to participate in the study, and that individuals' participation should be treated as separate from their regular duties; if project leaders cannot or will not abide by this condition, their project will be rejected as a prospective case. The principal investigator will then write to the recommended individuals to introduce the study and its objectives and to invite them to participate as research subjects. If these individuals express interest in participating in the study, the principal investigator will schedule a time to sit for an interview. Some interviews may be conducted remotely using internet-based video conferencing software, depending on participants' availability.

[1] See the case selection protocol for further details.

Describe the consent process. If alternate processes for seeking consent are planned (e.g. verbal, online, waiver), please provide a rationale and outline the procedure of obtaining and documenting consent and/or assent, where applicable.

Once individuals express their interest in participating, participants will provided with an informed consent document that outlines in more detail the goals of the study, the roles of the participant, how they will be recorded, how data pertaining to them will be retained, and the potential risks and benefits pertaining to their involvement. This document will also describe how participants' personally identifiable information will be managed and used. Participants will be asked to read and sign the document in order to obtain written informed consent. For interviews that will be held remotely using internet-based video conferencing software, participants will asked to send their signed informed consent documents in PDF format to the principal investigator. At the start of each interview the

researcher will reiterate participants' rights and ask them to orally reaffirm their consent before proceeding.

Is there a relationship between the study participants and the person obtaining consent and/or the principal investigator/s?

☒ Yes
☐ No

If yes, please explain the nature of the relationship, and outline the steps that will be taken to avoid the perception of undue influence.

One project that serves as a case in this research is the Covid-19 Immunity Task Force (CITF), which the principal investigator currently serve as postdoctoral researcher. Some of the participants will therefore be his colleagues. The interviews will remain structured and limited in scope, and will not touch on matters relating to other aspects of their work. Moreover, prior to and throughout their involvement as research participants, frank and open discussion will be encouraged regarding collective expectations and to articulate the boundaries between participants' relationships with the principal investigator as colleagues and as research subjects.

The principal investigator will consult with David Buckeridge, who leads the CITF, as one key community stakeholder to help devise a shortlist of projects that may serve as prospective cases.

Risk-benefit assessment

Describe the foreseeable risks to study participants. What risks are attributable to the research, including cumulative risks? Which risks are participants normally exposed to in the course of their clinical care or in their daily activities as they relate to the research questions/objectives?

Participation in this study does not involve any physical, psychological or legal risks. However, the principal investigator will be asking participants to share detailed information about

their work practices and work relationships, and public association with their responses may potentially disrupt or complicate their professional reputations. To mitigate against this potential harm, the principal investigator will give participants the option to render their responses confidential.

What procedures are in place to monitor and assess participant safety for the duration of the study?

Prior to each interview, and as part of the procedure for obtaining informed consent, participants will be asked about whether they want to render their responses confidential. Immediately after each interview, participants will be given an additional opportunity to reflect on their responses, and will be prompted to either confirm or alter their decision regarding whether or not to maintain confidentiality. Furthermore, for participants who have not requested that their responses be treated as confidential immediately before and after the interview, a follow-up email will be sent one week after the interview to reiterate the option to render their responses confidential.

Describe the potential benefits of the study for: (1) the study participants; (2) the population under investigation, and (3) the field of research.

This study contributes to the development of better epidemiological data-sharing infrastructures by articulating social, collaborative and discursive aspects of data harmonization, and how these factors relate to, overlap with or conflict with technical, institutional and epistemic factors. By explicitly framing data harmonization as a social and collaborative activity, we may devise more effective data-sharing infrastructures that better support the contextualization of data and enhance their value in contexts of data reuse. This work therefore poses new ways to document how epidemiologists mobilize distributed records in the constitution of synthetic knowledge and helps develop practical solutions that enable greater reflexivity. Additionally, this study may directly benefit participants by framing the experiences they address during interviews in ways that they might not have otherwise considered, thereby encouraging greater reflexivity in their own work.

Privacy and confidentiality

Please describe the measures in place for meeting confidentiality obligations. How is information and data safeguarded for the full cycle of the study: i.e. during its collection, use, dissemination, retention, and/or disposal?

The specific circumstances that frame each case are significant factors that will shape the findings, and the study will benefit from participants' consent to associate their identities with their interview responses. However, they may choose to render their interview responses confidential while maintaining their role a research participant. Participants may change their decision regarding whether or not to associate their identities with their interview responses up to one week after the interview, at which point the principal investigator will begin transcribing and analyzing the records pertaining to the interview. Participants will be reminded about this option immediately after the interview and one week following the interview via email.

The study engages with a relatively small community, and there is minimal social risk that others may be able to determine the identities of those whose research practices and professional relationships are being documented, even if their responses are rendered confidential. To address this issue, if any single participant from a case decides to render their responses confidential, the responses of all participants pertaining to that case will be rendered confidential as well, and the identify of the project that serves as the case will be obfuscated too.

In situations whereby a participant decides to render their responses confidential, or has their responses rendered confidential due to another member of their case deciding to do so, only the principal investigator will have access to records containing un-obfuscated information that may identify them. These un-obfuscated records, which may include audio and video records of interview sessions, as well as unedited transcripts and textual notes containing information that may reveal the participants' identities, will be kept in secure and encrypted media, and destroyed within five years of concluding the study, which provides sufficient time to revisit the data and produce additional research outputs. However, edited transcripts scrubbed

of all information that may identify research participants may be kept, published and archived. If participants consent to maintaining association between their responses and their identities, un-obfuscated records and transcripts may be kept, published and archived.

The study is committed to adhering to fundamental data security practices, including those specified in McGill University's Cloud Directive which regulates the curation of sensitive research data. Physical records will be kept in a locked drawer in secure workspaces, either at McGill University's School of Public and Global Health or at the principal researcher's home office. Digital records will be stored on encrypted and password-protected drives and on secure servers approved or managed by McGill University under the Cloud Directive.[2]

[2] Refer to the data management plan for further details on how information pertaining to this project will be collected, curated and shared.

Recordings of remote interviews conducted using internet-based video conferencing software will be made using the software's built-in recording tools. Only video conferencing software approved by the Cloud Directive will be used. Participants will be instructed to disable their microphones or video cameras prior to initiating recording if they have opted to not be recorded through these media. The researcher will record all media locally and refrain from using any cloud services to store or modify the records which the video conference software may provide.

If a contracted cloud/storage service provider or online survey tool is used, provide information on the service provider's security and privacy policy, location of its servers, data ownership, and what happens to the stored data after the contract is terminated. For more information, please consult the University's directive.

The study uses file-sharing software hosted by the Covid-19 Immunity Task Force at McGill University's School of Public and Global Health to backup all files maintained for this study. These backups will include files containing information that might reveal participants' identities. The software used to manage these backups is managed by McGill University and has been approved for storing sensitive research data by the Cloud Directive.

The study may use the secure GitLab instance hosted by the surveillance lab within the Clinical and Health Informatics Research Group at McGill University to store and track changes to sensitive research data. This software is managed by McGill University and has been approved for storing sensitive research data by the Cloud Directive.

The study maintains a website where the principal investigator shares documentation that supports the study and reflects on the work as it progresses. This is hosted using GitHub Pages and is backed up using Dropbox. No sensitive research data will pass through these services.

Recordings of remote interviews conducted using internet-based video conferencing software will be made using the software's built-in recording tools. Only video confering software approved by the Cloud Directive will be used. Participants will be instructed to disable their microphones or video cameras prior to initiating recording if they have opted to not be recorded through these media. The researcher will record all media locally and refrain from using any cloud services to store or modify the records which the video conference software may provide.

Please explain any reasonable and foreseeable disclosure requirements (e.g. disclosure to third parties such as government agencies or departments, community partners in research, personnel from an agency that monitors research, research sponsor, the REB/IRB, or regulatory agencies).

No disclosure requirements are foreseen.

If there are plans for retaining participant and/or study data for future use, please describe the context for its use, requirements for potentially re-contacting study participants and consent, and how the data will be stored and maintained for the long term.

Research data will be published in compliance with ethical standards for sharing open social science research data. Records that contain personally-identifying information pertaining to participants who have requested that their responses be rendered confidential and to those who have had their responses

rendered confidential due to another member of their case deciding to do so will not be published.

The database containing codings, memos and trends deriving from qualitative data analysis will be published only after being scrubbed of all personally-identifying information pertaining to participants who have requested that their responses be rendered confidential and to those who have had their responses rendered confidential due to another member of their case deciding to do so.

The principal investigator may follow up with the leaders of the data-sharing initiatives that serve as cases for this project to share the results with them and to present them with constructive feedback deriving from the study's findings. The principal investigator may also invite select participants to collaborate on a position paper advocating for reforms based on the project's findings.

Secondary use of data studies: if the study involves data linkage, please describe the data that will be linked and the likelihood that identifiable information will be created through the linkage.

This project does not rely on data deriving from other studies. The data may be reused in related work being undertaken under the same grant and by those who access the openly accessible data after they are published.

Managing conflicts of interest

Conflicts of interest do not imply wrong-doing. It is the responsibility of the investigator to determine if any conflicts apply to any person/s involved in the design and/or conduct of the research study or any member of their immediate family. Disclose all contracts and any conflicts of interest (real, perceived, or potential) relating to this research project. Conflict of interest may also arise with regard to the disclosure of personal health information.

☒ Not applicable. There are no conflicts of interest to disclose.

☐ Yes, there are conflicts of interest to disclose.

If yes, please describe the conflicts of interest (real, potential, and perceived), and the procedures for managing declared conflicts. Not applicable.