Community Engagement and the Ethical Governance of Canadian COVID-19 Biobanks

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Abstract

Canadian COVID-19 biobanks are valuable resources for public health research on the SARS-CoV-2 virus and will continue to be so in the coming years. As is true for all biobanks, it is necessary to ensure that these biobanks are well-governed to ensure their sustainability and ethical conduct. However, Canadian COVID-19 biobanks were established under the pressure of distinct challenges, such as time and physical barriers. The impacts of these barriers were exacerbated by a lack of pre-existing guidance on developing biobank governance policies within the context of a public health emergency. The literature has since offered guidance to help define ethical biobank governance during a public health emergency; however, there is a notable gap on the role of community engagement for such COVID-19 biobanks. Beyond the pandemic context, biobanks are increasingly turning to community engagement committees or other community engagement strategies to improve the trust, relevance, and transparency of biobank research. In this thesis, I examine the role of community engagement in biobanking in the context of Canadian COVID-19 biobanks. To consider how this is being managed in the Canadian COVID-19 context, I analyzed the available internal governance policies of Canadian COVID-19 biobanks to determine the extent of their community engagement efforts. I informed this document analysis with an assessment of Canadian and international guidance on biobank governance, as well as a literature review on the topic of good governance of COVID-19 biobanks.

Résumé

Les biobanques canadiennes de COVID-19 sont des ressources utiles pour la recherche en santé publique portant sur virus SARS-CoV-2 et le seront encore au cours des années à venir. Comme pour toutes les biobanques, il est nécessaire de garantir que celles-ci sont bien gouvernées, afin d’assurer leur viabilité ainsi que leur respect de normes éthiques. Cependant, les biobanques Canadiennes de COVID-19 ont été établies sous des contraintes particulières, tels que le (manque de) temps et la distanciation physique. L'impact de ces contraintes a été exacerbé par l'absence de plan d’intervention portant sur les politiques de gouvernance des biobanques dans le contexte d'une situation d'urgence en matière de santé publique. Depuis, la littérature propose des pistes pour aider à définir une gouvernance éthique des biobanques en cas d'urgence de santé publique. Toutefois, il existe une lacune notable en ce qui a trait au rôle des comités d'engagement communautaire pour ces biobanques de COVID-19. Au-delà du contexte de la pandémie, les biobanques se tournent de plus en plus vers des stratégies d'engagement communautaire pour améliorer la confiance, la transparence et la pertinence publique de la recherche sur les biobanques. Dans cette thèse, j'examine le rôle de l'engagement communautaire dans le contexte des biobanques canadiennes de COVID-19. Afin d'examiner la façon dont ce rôle s’opère dans le contexte de la COVID-19 au plan canadien, j'ai analysé les politiques de gouvernance interne disponibles des biobanques de la COVID-19 canadienne afin de déterminer l'étendue de leurs efforts en matière d'engagement communautaire. J'ai informé cette analyse documentaire en évaluant les directives canadiennes et internationales sur la gouvernance des biobanques, ainsi qu'en procédant à une analyse documentaire sur le sujet de la bonne gouvernance des biobanques COVID-19.

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Contributions of Authors

Emily Doerksen designed and conducted this project, and wrote the introduction, body, and scholarly discussion and limitations sections of this thesis. The methods sections was completed with the guidance of Therese Knoppers and the literature review component of this thesis was completed with the support of Erica Monteferrante. This work was completed under the supervision and financial support of Professor Ma'n H. Zawati. This project was supported and by funding grants from the Jewish General Hospital, Autism Speaks, Fonds de Recherche du Quebec, Genome Canada, and the Public Health Agency of Canada.

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List of Abbreviations

CAB: Community Advisory Board

CE: Community Engagement

COVID-19: Coronavirus Disease 2019

ELSI: Ethical, Legal, and Social Implications

ICF: Informed Consent Form

REB: Research Ethics Board

SARS-CoV-1: Severe Acute Respiratory Syndrome Coronavirus 1

SARS-CoV-2: Severe Acute Respiratory Syndrome Coronavirus 2

SOPs: Standard Operating Procedures

TCPS-2: Tri-Council Policy Statement 2

Chapter 1: Introduction

1.1. Thesis Context

Biobanking has become a cornerstone of genomics, public health research, and epidemiological interventions.[1] As such, when the Coronavirus Disease 2019 (COVID-19) pandemic began in December 2019, biobanks specific to the SARS-CoV-2 virus were created worldwide to help advance knowledge on COVID-19.[2] When the COVID-19 pandemic was first declared, there was great urgency to understand the viral characteristics of the SARS-CoV-2 virus. Research interventions were described as "…paramount to developing effective mitigation and treatment strategies".[3] At this time, there was an equal need for researchers to internationally collect and share biological samples of both patients infected with COVID-19 and healthy volunteers with negative COVID-19 results.[2] Sharing COVID-19-related genetic data at this time was imperative, as little was known about the disease's viral transmission, prognostics, and infection mechanism.[3]

Biobanks are large collections of, most often, human biological samples and associated data that are stored for the purposes of engaging in future, often initially undefined, health or medical research.[4] Human health biobanks can consist of a variety of human biological materials (e.g., genetic material, blood, saliva, etc.) and are stored with associated biobank-participant data (e.g., age, sex, medical condition, health record information).[4] Biobanks can generally be typed as either population or disease specific biobanks.[5] Population-specific biobanks are biorepositories that are established to study or identify genetic risk factors or other external factors that contribute to the presence of diseases. [5] A prime example of a population biobank is the UK biobank, which collects biological and medical data from UK residents aged 40-69.[5] These data provide insight in disease expression within a population, and are often used to identify disease biomarkers or disease susceptibility within a population.[5] Alternatively, disease-specific biobanks collect biological samples relating to a particular disease and correlate the phenotype of a disease with other health data to develop potential therapeutic solutions.[5] Some disease-specific biobanks exist to optimize treatment for a diseases (e.g., Type 2 diabetes), better understand rare diseases, or target new diseases, as we see with COVID-19 biobanks. Disease-specific biobanks can help determine responses to treatments and identify molecular targets or biomarkers for a specific disease or disease.[5]

Biobanks are valuable resources for health research in addressing such epidemiological concerns; however, biobanks also raise ethical concerns, as they house biological samples and large datasets of genetic material and their associated donor information.[4] As an approach to address such ethical, legal, and social implications (ELSI) associated with their operations, biobanks rely on governance protocols and policies to manage their conduct.[5] Developing these policies requires time, expertise, and collaboration between the biobanking community, and, oftentimes, the public.[5] However, COVID-19 biobanks have been subject to time constraints that biobanks developed outside a pandemic landscape are not.[6] Despite such constraints, COVID-19 biobanks, like all biobanks, require considerable thought into the potential ELSI which may surround their operations.[7,8] This is because biobank governance policies help to balance the tension between sufficiently protecting participant data while allowing for future use of samples for research purposes. Biobanks serve to balance the interest of the public in improving the epidemiological understanding of disease and the risk of participants who contribute to biobanks.[9] The literature explains that good governance necessarily involves transparency, accountability, and oversight. Transparency is described as facilitating trust between the public and the operations of biobanks.[10] This concern for governance, the role of trust and transparency as facilitators between the operations of biobanks and the public, in addition to the time pressures imposed on COVID-19-specific biobanks, is the general context against which this thesis project is set.

1.2. Topic Background

Biobanks are governed in a twofold manner, both externally and internally. Externally, biobanks are governed by ethical norms, laws, and policies, from which they cannot deviate. A key resource in Canada for external governance of biobanks, as well as bioethical consideration overall, is the Tri-Council Policy Statement-2.[11] In effect, the normative regulations found within the TCPS-2 apply to all publically-funded research biobanks operating within Canada.[11] Concerning their internal governance, biobanks have more opportunities to deviate from homogenous models of governance, imposed by external laws and regulations. The internal governance of a biobank consists of several committees to oversee its operations. The International Agency for Research on Cancer (IARC) compiled governance recommendations for biobanks to create a consensus and guiding document according to leading normative and regulatory organizations.[12] This document, explains that the 'essential' committees in biobank governance include a: (1) biobank executive committee or steering group; and (2) laboratory safety and biosecurity committees [5]. 'Strongly recommended' committees for internal biobank governance include (1) a scientific oversight committee; (2) an Ethics oversight committee; (3) an operations management committee; (4) a data and sample access committee. In addition, the IARC's 'Recommendations for Biobanks' indicates that biobanks may choose to incorporate a quality management committee as well as a public engagement committee in their governance structure.[12]

It is not only necessary that biobanks develop internal governance policies, but also that they are well developed. The IARC indicates that a good governance framework for biobanks is required to have clear organizational structures clearly articulating their approach concerning oversight committees, policies, and procedures, according to the size and activities of the biobanks.[12] Accordingly, biobank governance is not 'one-size-fits-all'.[12] There is an opportunity for variability between biobanks concerning how their internal governance structures are ordered and concerning which committees they include, as some committees are not considered necessary components for oversight. For example, IARC remarks that quality management committees and public engagement committees are 'optional,' oversight structures. Regardless of this optional quality, biobanks are increasingly turning to community engagement strategies to increase public support for their operations.[13]

Biobank public/community engagement committees exist along the greater continuum of participatory research methodologies. Community engagement (CE) as a research methodology has enjoyed a surge in use in the domain of public health research in recent decades.[14] Both CE and 'community' can vary in their scope from biobank to biobank. In the context of this thesis, CE is understood as any strategy, method, or approach to involve, inform, consult, or seek contribution from a group of individuals who may be impacted by the activities of a biobank. CE recognizes that research participants and patients are the people most impacted by research outcomes and health care, and thus should have a greater say in the research concerning them.[15] As such, CE aims to improve the relevance of research outcomes through meaningful engagement with community groups.[15] CE methodologies aim to address the common disconnect between the needs or expectations of the community being researched and research outcomes. Concerning bioethics, CE is often framed as espousing the ethical values of solidarity, distributive justice, and reciprocity.[16]

When CE is done well, it promotes the voice of the public, improves trust between the public and researchers, and is argued to enhance ethical procedures (e.g., such as informed consent, re-use of data, secondary use of data).[17] However, when done incorrectly, CE can be perfunctory, and at its worst, exploitative of community groups and even harmful to such groups. As such, it is important to ensure that researchers who are intending to pursue CE efforts are held accountable and that such efforts are grounded in the ethical principles of solidarity and distributive justice.[17] As mentioned, these are ethical values that CE is considered to espouse and are fundamental to its core. CE should not simply be seen as one approach biobanks may choose to employ in their governance structures, but as an ethical imperative which encourages trust and transparency between biobank donors, the public, and biobanks.[18]

With respect to biobanks, CE is argued to improve research practices, maintain trust between the public and researchers, and improve the health outcomes of research projects.[18] In addition, CE may strengthen communication channels between partners to ensure that projects can "evolve into lasting collaborations".[19] IARC's document on best practices for biobank governance notes that public engagement committees "…could help biobank personnel and associated researchers to better understand public opinion".[12] CE in biobanking can relate to a wide variety of practices to incorporate community perspectives, but CE entails "…deliberative approaches to provide a shared discursive space for the public and experts".[13] Despite this, there is a considerable gap in the literature articulating biobank best practices concerning CE as a form of governance during the COVID-19 pandemic. This gap will be identified in the next section of this thesis, which consists of a literature review on good governance during the COVID-19 pandemic.

1.3. Review of the relevant Literature

The following section provides a review of the literature that exists in relation to the best practices for COVID-19 biobanks and their governance. The methodological approach for this literature review is explained in section 2.1.1. This review yielded 14 articles in total, relevant to the topic of the governance of COVID-19 biobanks. Accordingly, this literature review will discuss these articles, as well as why, at all, there was a biobank response to the pandemic and the role biobanks played in the pandemic, and the challenges that biobanks faced when focusing their operations to target COVID-19. The primary purpose of this literature review was to identify the concerns of the biobanking community during the pandemic with respect to the governance of COVID-19 biobanks and to identify commonalities, differences, and gaps among the current literature on the topic of COVID-19 biobanking and best practices or governance to inform the research question and direction of this thesis.

1.3.1. Biobanking as a Public Health Response to the Pandemic

Some academics and biobank experts commented on the role of biobanking during the pandemic began with the assumption that a modern public health response to the COVID-19 pandemic necessarily involves biobanking, such as Singh, Cadigan, and Moodley, who were direct in characterizing biobanks as a "public health imperative during the COVID-19 pandemic".[20] Similarly, Brothers Goldenberg, and Cadigan, remark that biobanks are vital resources for collecting and assessing COVID-19 biosamples. As a result, biobanks were expected to "step up" their research following the emergence of the SARS-CoV-2 virus.[21] Biobanks that were already operating for different purposes were expected to shift their operations to focus on SARS-CoV-2, while in other cases new biobanks were created to establish a COVID-19-specific biorepository.[2,22]

It is useful to consider why biobanks are deemed valuable in addressing the COVID-19 pandemic. Afolabi and Ilesanmi note that biospecimen collection and testing are necessary to improve disease diagnostics and comprehension, which is an especially urgent concern when confronted with an infectious, novel, disease.[23] Peeling and colleagues explain that biobanks were needed early on in the pandemic to increase the speed at which test development and evaluation for COVID-19 were available.[24] Accordingly, COVID-19 research became the priority of research institutions worldwide.[22]

Dissimilar to the 2003 SARS outbreak, researchers and biobankers during the COVID-19 pandemic prioritized an open science approach and encouraged international data sharing of biospecimens.[22] This openness allowed for improved methods of detection for COVID-19, testing measures, and an unprecedentedly quick response to the pandemic from the research community.[2] Global demands for collaboration and access to COVID-19 samples were heard by researchers, many of whom focused their efforts on working collaboratively to target the COVID-19 pandemic.[2] International data sharing was also facilitated by international consortia and calls from global health organizations, such as the WHO (World Health Organization), which quickly prioritized testing for COVID-19 to ensure "rapid point of care diagnostics for use at the community level".[25,24]

1.3.2. Time Pressures and Access to COVID-19 Biosamples

Multiple factors were explained to contribute to the urgency for the biobank community to collect COVID-19 biosamples. First, a biobank response to the pandemic was fueled by the challenges imposed on the biobanking community to collect COVID-19 samples from hospitalized patients for research purposes.[2] In addition, the rapid speed at which COVID-19 spread worldwide required rapid testing and assessment of COVID samples.[24] Within a broader context, a biobank response was also motivated by strict public health measures such as quarantines, interruptions to businesses, mask mandates, and curfews, which were argued as impeding “individual movement”.[26,22] Indeed, while all such measures were implemented to protect the public from the virus by preventing further community-level infection they were done at the expense of regular social activities and had a considerable impact on global economies.[22] In effect, the time pressures experienced by biobanks in the first year of the pandemic were due to the role of COVID-19 samples in developing vaccines, drugs, and treatment methods for SARS-CoV-2.[27]

Simeon-Dubach and Henderson remark that because of the pandemic, biobanks “...were instructed to put their activities in maintenance mode, to convert their operations to collection and testing facilities, or to rapidly realign themselves to allow the collection, processing, and storing” of COVID-19 biosamples.[2] Biobanks were required to rapidly gain insight into the viral pathogenesis of the novel coronavirus and develop new and robust data-sharing policies for access to high-quality COVID-19 biospecimens.[22] In turn, biobankers were expected to shift their attention and focus on COVID-19 research or establish new biobanks specific to COVID-19. Establishing a new biobank demands considerable thought and deliberation into the model a biobank may employ (e.g., centralized, federated, decentralized, or hybrid), and their governance policies, including its approach to consent, data collection, quality assurance, safety measures, in addition to ELSI associated with the use and sharing of biospecimens.[22] Much of this process was explained to be complicated by a lack of sufficient guidance specific to biobanking during a global health emergency, and this challenge was often highlighted in the literature.[28,29,2,20,30]

1.3.3. Challenges with Guidance/ Lack of Pandemic-Preparedness Governance Guidelines

Regardless of whether a pre-existing biobank diverted its attention to target COVID-19 research or if a biobank was created for the same purpose, much of the literature explained that biobanks faced difficulties with respect to a lack of clear and pre-existing guidance for biobanks in response to potential pandemics.[28,29,2,20,30] Such authors identified a lack of guidance created in anticipation of a pandemic or similar global health emergency. [28,29,2,20,30] This lack was criticized by the literature to have negatively impacted the efficiency and early efficacy of biobanks responding to the COVID-19 pandemic.[28] This gap in guidance posed operational and organizational challenges to biobanks, which was exacerbated by time pressures and physical barriers stemming from the infectious nature of SARS-CoV-2.[20]

Yadav and colleagues remarked that there were no pre-existing guidelines for biobanking during a pandemic, although current international standards remained relevant to guide the governance of biobanks during the pandemic.[30] In contrast, survey results from Allocca and colleagues indicated that pre-existing guidelines did not provide sufficient clarity, nor updated information "reflecting the rapidly and continuously evolving" pandemic situation, particularly in the first year of the pandemic.[28] Moreover, the authors remark that biobanks must adhere to specific standards to ensure the quality of research and that while these sorts of resources were available to biobanks, it is not always clear to whom these resources are directed or how they are best implemented.[28]

A similar challenge to developing governance policies is that biobanking typically occurs within research institutions, such as universities or hospitals. As a result, biobankers may not see themselves as such, but as general health researchers.[2] Due to this, adjusting or creating governance protocols that account for pandemic measures may have been particularly challenging for researchers, as researchers who contribute to biospecimen research collections might not see themselves as biobanking, and therefore may not adhere to the guidelines in place to guide biobanking.[2] As a result, biobanks could face issues with their governance protocols and

ELSI considerations regardless of whether they were newly established biobanks created in response to the COVID-19 pandemic, or if they were pre-existing collections redefined to target COVID. Effectively, Simeon-Dubach and Henderson explain that these sorts of challenges resulted in SOP compliance issues among biobanks during the pandemic, due to the lack of harmonization and standardization in biobanking.[2]

1.3.4. Biosafety

Interrelated with the challenges imposed on informed consent, biosafety was a prominent concern for biobankers during the pandemic. This is to be expected, given that SARS-CoV-2 is a highly transmissible respiratory illness. Allocca and colleagues argue that biosafety issues in biobanking can be addressed by establishing clear guidance via SOPs and preventative training of staff for risk management.[28] Yadav and colleagues similarly remark that SOPS are needed to ensure best practices in biosafety when faced with public health emergencies.[30]

The results of Allocca and colleagues's survey of biobanks targeting COVID-19, conducted in collaboration with ISBER, found that the primary concern of most biobanks was the safety of biobank personnel.[31] Afolabi and colleagues explain that the diagnostic role of biobanks meant that an increased number of COVID-19 biobanks emerged to conduct research, resulting in large numbers of COVID biosamples, and a greater need for guidance in biosafety.[23] Another reason for the concern for biosafety may be because of the influence of the WHO, which provided early guidelines for the safe collection and storage of COVID-19 biosamples.[23] Biosafety was explained to impose organizational challenges on biobankers because strict biosafety protocols made it difficult to access the data.[20] Allocca provided recommendations, noting that prepared biobanks should have established priorities in case of public health emergencies, and prioritized personnel safety and emergency communication.[28,31]

1.3.5. Informed Consent

Another challenge presented by the literature relates to difficulties in obtaining informed consent for COVID-19 biobanks. Informed consent is described as an ethical cornerstone of research involving human participants, as it is the tool to implement the bioethical principle of autonomy.[32] Informed consent is obtained through written consent forms which are provided to research participants by researchers. Due to the infectious nature of the SARS-CoV-2, informed consent processes had to be altered to avoid contact between donors and researchers.[26]

Gao and colleagues note that the logistical challenges in obtaining informed consent for biobank donation during the pandemic "...may undermine autonomous decision making" (Gao, 2021). Collecting samples from non-hospitalized volunteers was nearly "impossible" due to quarantine measures, while hospitalized patients may not have had sufficient capacity due to illness to engage with the consent process.[19, 25, 26] Moreover, proxy consent was complicated as visitors were not permitted to the hospital.[27] Indeed, the infectious nature of the pandemic meant that typical approaches to obtaining informed consent were not available to researchers. As such, altered and even innovative approaches to obtain informed consent for collecting biosamples from COVID-19 patients became necessary.[26]

1.3.6. Community Engagement

In discussing the COVID-19 emergency preparedness in Lagos, Nigeria, Abayomi and colleagues comment that the Lagos State Biosecurity and Governance Council, which was established to facilitate the emergency preparedness against emerging infections diseases, had an ‘underdeveloped (and therefore delayed) emergency plan to involving community and religious leaders on the council.[33] The authors comment that community and religious leaders “are huge influencers during outbreaks and play a pivotal role in the whole-of-society pandemic readiness that the WHO recommends for national responses”.[33] This commentary highlights that CE and community involvement are necessary contingencies for pandemic and epidemic preparedness. Regardless, it seems that the literature, on the whole, did not comment significantly on the topic of CE and good governance in a pandemic context. Of the total articles included for review, only 4 of 14 commented on CE in a meaningful capacity.[20,21,33] As such, one may conclude that the biobanking community did not prioritize discussions on the topics of CE and governance of COVID-19 biobanking. Regardless of why CE was not prominent in the literature, the result is that CE and governance of biobanks during a pandemic are under-discussed, meaning that there is a gap in expertise and consideration on the topic. However, the topic of CE was touched upon explicitly by Singh, Cadigan, and Moodley, Brothers Goldenberg and Cadigan, and Abayomi and colleagues.[19,20,32]

CE may provide valuable answers to the question raised by Brothers and colleagues, as well as Singh and colleagues, both of whom ask whether the pandemic has allowed for debate on the standards for ethical procedures.[20,21] These authors question if, because certain ethical standards were able to be circumvented during the pandemic, it was always ethical to do so.[21] For example, Brothers and colleagues explain that virtual strategies to consent research participants could easily become an ethical standard following the pandemic.[21] Singh, Cadigan, and Moodley remark that CE ensures fairness in how significant decisions are made in health research.[20] Moreover, they explain that CE is important in providing answers on how to approach informed consent, repurposing biosamples, and the acceptability of data sharing.[20] Accordingly, one could argue that CE is more important during public health emergencies, such as the COVID-19 pandemic than outside of a public health emergency, as far as the pandemic significantly impacted researchers' ability to adhere to commonplace ethical practices, such as obtaining traditional, written, informed consent.

The pandemic also provided opportunities for virtual CE and, according to Brothers and colleagues, a wider reach as to who was able to participate in CE.[21] Virtual CE helped to incorporate communities into the ethics governance process, as it created a channel of communication between community members and Research Ethics Boards during imposed periods of isolation.[21] However, it is important to recall that many community groups may not have easy or equal access to electronics or the internet which is known as the ‘digital divide’.[34] This divide limits the benefits that virtual CE may have in providing a voice for marginalized communities. Importantly, marginalized or LMIC (Low or Middle-Income Country) communities are often disproportionally impacted by the ‘digital divide’.[20] As a result, virtual CE efforts may limit the extent to which biobankers are able to meaningfully pursue CE within certain settings. However, Singh, Cadigan and Moodley explain that CE in LMIC is “...particularly important when members of marginalized communities are expected to participate in research, or when there are social and economic disparities between those conducting the research and those participating”.[20]. Such populations may not have ease of access to electronic platforms, which means that an increased reliance on electronic modes of conducting CE is not always appropriate or ethical.

Within Canada, the digital divide disproportionally impacts communities that have historically been made vulnerable or marginalized by unethical research, such as Indigenous groups, particularly Inuit and Northern Indigenous groups where internet access is scarce.[34] An overreliance on electronic methods for CE may not only exclude vulnerable community groups (such as unhoused people or people living in poverty) from offering their expertise, it also is antithetical to chapter 9 of the Tri-Council Policy Statement, which requires researchers to seek CE with Indigenous community groups they seek to research.[11] CE is done to improve the ethical conduct and relevance of research by hearing and taking into consideration the lived realities and expectations of community groups. Therefore, it is valuable to reflect on how and when CE may occur within the Canadian biobank context, not only to ensure transparency, accountability, and improved sustainability of biobanks but to ensure that CE is conducted well and with consideration into the lived realities and expectations of community groups.

1.3.7. Conclusion from Literature Review

Biobanks functionally represent a mutually beneficial relationship between those individuals operating biobanks and the public who benefit from the research done by biobanks. With this in consideration, it is an ethical good in and of itself to give a space for the public to have a voice in the governance of biobanks, as they are a necessary component of biobanking. This notion is reflected in the practice of CE, which serves to espouse the ethical concepts of solidarity, reciprocity, and justice. Regardless, little attention was given to the literature on the governance of COVID-19 biobanks in consideration of the effect that the pandemic had on biobank CE. This may indicate that CE efforts were not a priority for biobanks at the outset of the pandemic, or that pre-existing biobanks were not employing CE efforts to begin with. Both possibilities are of concern, given the documented benefits that CE offers to biobanks and their personnel.[20]

The literature suggests that the governance of biobanks was undoubtedly complicated by the pandemic. Experts in biobanking tended to focus on governance issues with data access, biosafety, and informed consent for COVID-19 biobanks. The commonality of these concerns within the literature implies that there will be more resources and SOPs on these topics available to biobankers, in the event of future global health emergencies. Whereas the relative lack of discussion on CE leads to the implication that future resources to guide emergency biobank procedures may overlook CE approaches. This would impact transparency between such biobanks and the community. This gap in the literature is what this thesis will seek to address.

1.4. Research Question

COVID-19 biobanks will remain important resources as the pandemic continues to progress. To ensure the sustainability of such biobanks and the ethical use of their samples, the governance frameworks of these biobanks should be well organized and compatible with the interests and needs of researchers and the public. Gille, Vayena, and Blasimme comment that the topic of biobank governance has attracted the interests of researchers and academics in the recent decade, particularly with respect to topics of data access, protection, confidentiality, and informed consent.[7] However, there is less attention given in the literature articulating the qualities of good community-engaged governance for biobanks. As such, this thesis argues that CE is an important quality of good biobank governance, and it seeks to address the above-mentioned literature gap, by mapping the approaches of CE for biobank governance, employed by pre-pandemic biobanks. These ideas are proposed in consideration of two interrelated research questions motivating this thesis. The first of these questions is:

> How have pre-COVID-19 biobanks employed ‘community engagement’ strategies as a component of their internal governance structure?

The time pressures imposed on COVID-19-specific biobanks in Canada justify an inquiry into the role and characteristics of the internal governance structures employed by Canadian COVID-19 biobanks. Assessing all components of Canadian COVID-19 biobanks in their governance structure is beyond the scope of this thesis. As such, this thesis focuses on their approaches to CE committees for their internal governance. This inquiry is proposed in consideration of the epistemic gap in the literature articulating good community-engaged governance during the pandemic, which may mean that CE has been under-utilized by biobanks created to address

COVID-19. Therefore, this research is also motivated by the following, second, research question:

> What is the current and future role for community engagement as a method of internal governance for COVID-19 biobanks in a Canadian context?

These research questions will be answered by first identifying approaches to community-engaged governance employed by pre-pandemic biobanks and identifying their core components, applicability, and similarities as well as differences. This will be informed by a review of the literature on CE and biobanking. Second, this thesis consists of a comparative document analysis of Canadian COVID-19 Biobank's governance policies. This will help to articulate the role of CE for good biobank governance, identify what methods of CE biobanks have made use of in the past, and provide insight into the potential form and scope of CE and biobank governance. This will help contribute to considering the future role of CE as a method of internal governance for Canadian COVID-19 biobanks.

1.5. Objectives

This research project was guided by 2 primary objectives:

(1) Investigating and documenting the scope of biobank CE committees which were in operation prior to the pandemic;

(2) Investigating the governing policies and consent models employed by COVID-19 biobanks in Canada and identifying the qualities of their CE framework.

Chapter 2: Methods

To begin my research, I conducted a narrative literature review on the topic of the best practices and good governance of COVID-19 biobanks. The results of this literature review are given in the introduction of this thesis under the heading “COVID-19 Biobank Governance: The Literature.” The process of identifying articles for review is described in section 2.1.1 of the methods. The purpose of this literature review was to introduce and provide an overview on the topic of governance and COVID-19 biobanks and identify gaps in the literature on this topic.

The other primary components of this thesis were a review of the normative guidance for the best practices in biobank governance, a comparative literature review of approaches to CE in biobanking, and a document analysis of the CE governance policies of Canadian COVID-19 biobanks. A review of the normative guidelines allowed for a comparison between the results of the literature review on the topic of governance and COVID-19 biobanks. Additionally, a normative document review provided insight and guidance with respect to best practices in CE for biobanks. The comparative literature review demonstrated the scope of strategies for CE efforts used by biobanks before the pandemic. The review on CE strategies, as well as the guidance offered by normative documents on CE, helped establish a basis of comparison for Canadian COVID-19 biobanks and their approaches to following the document analysis component of this thesis.

2.1. Literature review of best practices in biobank governance

I conducted a narrative literature review on the topic of COVID-19 and biobank governance. A narrative literature review is understood as a qualitative research methodology useful for synthesizing previous articles or documents written on a subject.[35] The primary purpose of such a review is to provide a comprehensive overview and appraisal of a topic of interest, as well as to identify the current gaps in knowledge on a topic.[35] In addition, a narrative review can further define and refine a research question.[35] A narrative review on best practices in biobank governance was the first point in developing this thesis, and it contributed to refining my scope of inquiry. The search string used to search for articles was developed in October 2021.

This review sought articles which discussed the ethical, legal, regulatory, and governance issues associated with the establishment, use, and/or operation of COVID-19 Biobanks. It entailed a multi-step methodology which involved electronic database searches of academic peer-reviewed literature. This was followed by a snowball-search technique, wherein the references of articles chosen for inclusion were scanned to capture additional relevant documents.

To identify literature on this topic, a search string was developed which was used for all database searches for this subject. Searches were conducted in October 2021. The final string used for this narrative review was: *(Biobank OR biomedical specimen bank/standards OR biomedical specimen bank/methods OR biorepository OR factual databases OR genetic databases OR "Health Information Management"[Mesh] OR specimen handling/standards OR specimen handling/methods) AND (COVID-19 OR SARS-CoV-2 OR pandemic) AND (Ethics OR Governance).* Three separate searches were conducted using Embase, ProQuest, and PubMed.

Scopus produced 36 results and ProQuest produced 10, and PubMed revealed 36 results, for a total of 85 articles which were imported into EndNote (see: figure 1)

Articles were included if they were (1) full-text, peer-reviewed; (2) written in English; (3) on the topic of best practices in biobank governance; and (4) published between 2003 to the time of the initial search (October 2021). This date range was chosen to include sources on this topic which may have been written in response to the SARS-CoV-1 outbreak of 2003. Despite this date range, no relevant documents on this topic were revealed through searches. As a result, I conducted a fourth search using Google Scholar and narrowed the date range of this fourth search from 2003-2010, which again did not reveal any articles specific to SARS-CoV-1 and biobank governance.

The 85 documents were then reviewed using Rayyan, an online tool for systematic review, to assess them according to eligibility criteria.[36] 13 duplicate articles were removed, leaving 72 articles for title and abstract screening. Following title and abstract screening, 57 articles were excluded for several justifications, including being too narrow in scope, the incorrect article type, or an irrelevant topic, and as a result were not eligible for inclusion. A total of 15 articles were included for full-text review. Following a full-text review, 8 articles were found to meet the inclusion and exclusion criteria of this review. Through citation-chaining the 8 included articles, an additional 6 articles were found to be relevant to the topic of the review. A total of 14 articles were included in the review. Figure 1 provides an overview of the described screening process.

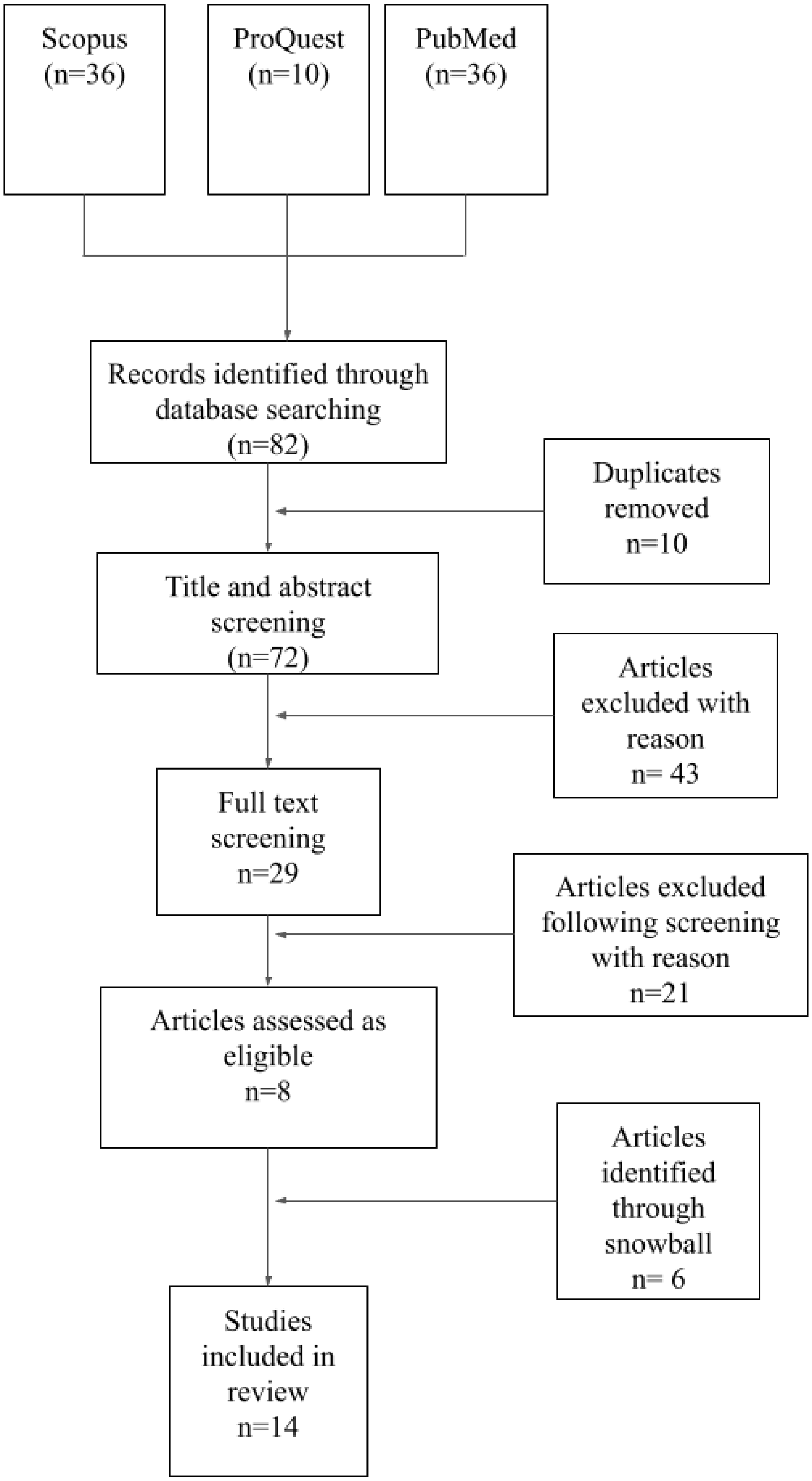

Figure 1: Flow chart of literature selection screening process for the topic of best practices in biobank governance

2.2. Identification of Normative documents

In addition to a literature review, I conducted a normative document review pertinent to best practices in biobank governance in Canada. With respect to this thesis, normative documents are understood as prescriptive texts which provide guidance on the standards and best practices for biobanks and biobank governance. As my inquiry focuses on Canadian biobanks, I included normative documents written for either an international audience (therefore relevant to the Canadian context) or Canada-specific documents. I chose not to include normative documents originating from and specific to biobanking in the EU, USA, and Australia, although documents from these countries were revealed through my search strategy. This decision was made in order to narrow the scope of this component of my search and ensure that the normative documents assessed provided relevant prescriptive guidance and regulatory expectations for biobanks operating in Canada.

I chose to include a normative document review to articulate the external influences on biobank governance and to identify if, and how, the information offered in these documents may vary from the literature. Notably, studies from the literature review on biobank best practices did not discuss the topic of CE, except three articles.[20,21,33] However, a majority of normative documents on this same topic dedicated discussion to the topic of CE, public engagement, or similar derivatives of the concept. This gap influenced my decision to incorporate a review of previous approaches used by biobanks for CE, in order to understand how COVID-19 may have impacted CE.

Kleiderman and colleagues informed the methodology for the normative document review.[37] In their article, the authors identified normative documents using the HumGen international database of national, regional, and international guidelines and policies relating to human genetics. However, this database was regrettably no longer operational nor maintained at the time of my search. Furthermore, I was unable to identify any similar databases or collections of resources to aid in conducting a systematic search for normative documents with respect to biobanking. As such, I was required to develop a new search approach to ensure I captured the appropriate documents for this review. I chose not to use Google Scholar to identify sources, as this would only reveal academic or peer-reviewed articles in place of normative documents because it is a source for scholarly literature. With this in consideration, I instead queried Google Advanced using the search string '*normative documents for biobank best practices'* and excluded results of peer-reviewed articles. I scanned the results of this search to identify normative documents written in English, published from 2003 to the present time of the search. This approach yielded 70 total results. I then screened the title of these results individually and appraised them according to relevance and document type. This approach resulted in 4 normative documents relevant to the topic of best practices in biobank governance in Canada. To identify additional normative documents, I consulted a list of normative documents identified in Zawati, 2021.[38] This revealed an additional 4 normative documents relevant to my search. A list of these results is found in table 1.

Table 1: Normative Documents Included for Assessment

Institution	**Document**	**Year**	**Region of origin/ influence**
Council for International Organization of Medical Sciences (CIOMS)	International Ethical Guidelines for Health-Related Research Involving Humans	2016	International
Fonds de la Recherche en Santé du Québec (FRSQ)	Governance Framework for Data Banks and Biobanks	2006	Canada
Interagency Panel on Research Ethics	Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS-2)	2018	Canada
International Agency for Cancer Research (IARC)	Biobank Recommendations: Section 3	2018	International
McGill University	Guidelines for biobanks and Associated Databases	2015	Canada
OCED	OCED Guidelines on Human Biobanks and Genetic Research Databases	2009	International
Policy Partnership Project for Genomic Governance	P3G Model Framework for Biobank Governance	2013	Canada
World Medical Association	Declaration of Taipei on ethical considerations regarding health databases and biobanks	2016	International

2.2. Approaches to Community Engagement Comparative Group

I conducted a comparative narrative review of approaches to CE used by biobanks prior to the COVID-19 pandemic. A narrative review was selected in favour of a systematic review, as the focus of the review was intentionally broad, so to capture the variety of approaches used by biobanks as strategies in CE, and because the type of literature I sought to identify used qualitative or mixed methods.[35] To identify relevant search terms, I conducted a search using the PubMed and SCOPUS databases. Keywords were informed by two prime example papers on the topic of interest (see: Lemke and colleagues., 2010; Chang, 2019).[39,40] The final PubMed keywords used were: *("Bioban*") AND ("Community engagement" OR "Public Engagement" OR "Participatory").* The results were assessed according to the following inclusion criteria:

(i) full-text peer reviewed articles from 2003-2020;

(ii) discuss or represent actual approaches to community engagement in governance **or** represented the perspective of community of individuals who donated to a biobank or who are implicated by the results of the biobank's research; and

(iii) Specific to human health biobanks.

Articles were excluded for assessment if they discussed CE in biobanks without specific attention to CE as a form of governance or did not meet any of the above inclusion criteria.

A PubMed search using the above approach produced 81 results. A second search using Scopus produced 201 results, for a total of 282 total articles. Following the removal of 60 duplicate articles, a total of 222 articles were screened for abstract and title review using Rayyan, and 177 articles were excluded with reason, according to the above eligibility criteria.[36] After this, I conducted a full-text screening of articles and excluded an additional 26 articles. This left a total of 19 articles which were found to be eligible for qualitative analysis. I then scanned the references of the eligible articles to identify additional papers via citation scanning. This approach revealed an additional 6 articles, for a final number of 25 articles included for qualitative analysis. The screening process employed for this narrative review of CE and biobank governance is outlined below in Figure 2.

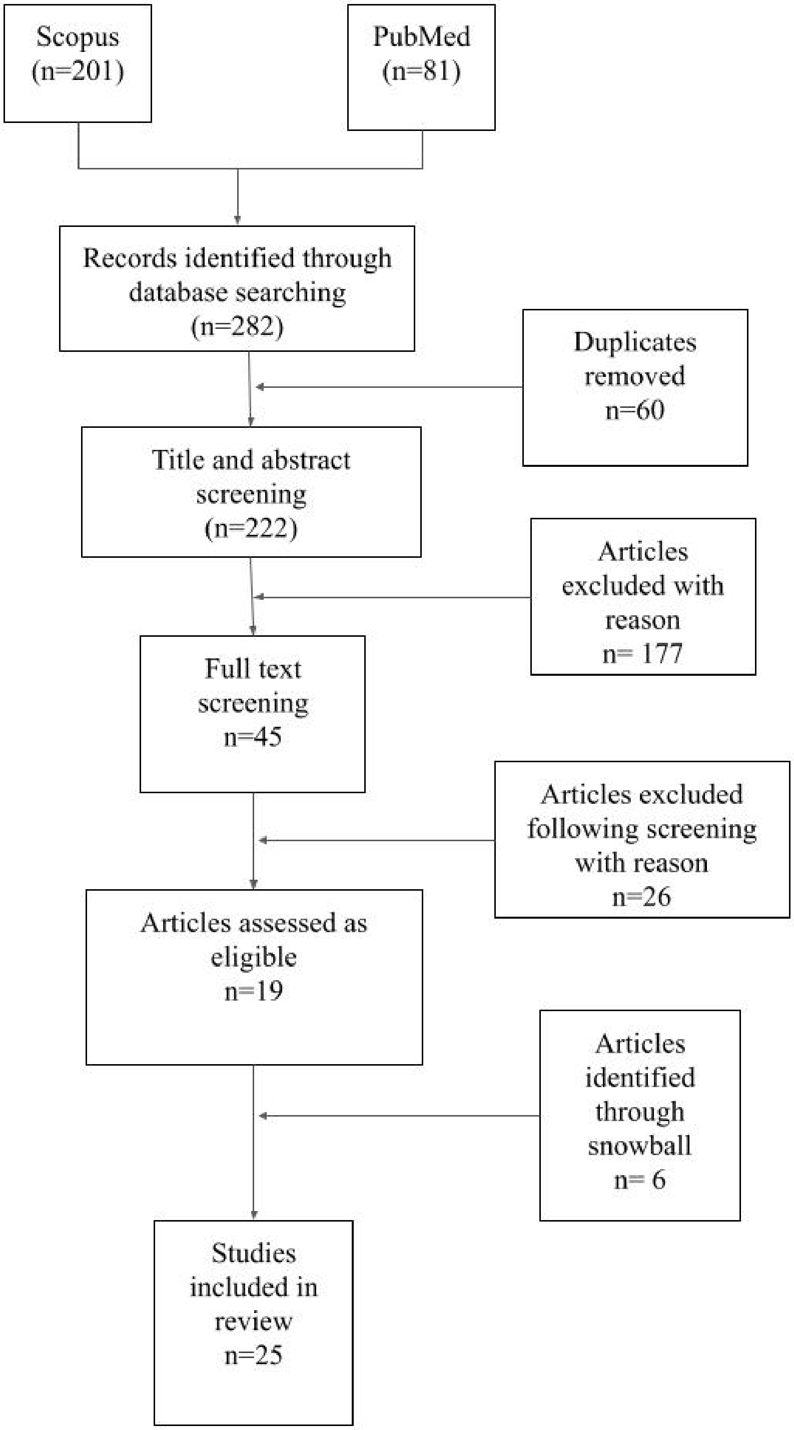

Figure 2: Flow chart of literature selection screening process for the topic of community engagement and biobank governance

The goal of this section of my thesis was to document practices in CE used by biobanks, which were in operation prior to the pandemic. I sought to include such biobanks to articulate CE methods employed by biobanks under ideal circumstances, and to illustrate the scope of approaches to CE. I extracted articles according to the strategies that they used for CE in their governance approaches, documenting the methods they employed, the role the community played in the governance strategy, and any associated challenges or benefits experienced during the process and described in the articles. After extracting and documenting this information, I organized these strategies according to the International Association for Public Participant (IAP2) Canada's "Spectrum of Public Participation" (Figure 3).[41] I also selected 2 examples, each, of CE strategies from the USA, Canada, and the international community of biobanking to highlight in the results section of this thesis.[1]

IAP2 explains that the Spectrum of Public Participation "was designed to assist with defining the quality of the public's role in a public participation process," including, although not limited to, health research.[41] The spectrum is used as an international standard, and therefore was considered suitable for this thesis to document and categorize the scope of CE efforts from by narrative review, which included literature from the international biobanking community. Such a spectrum aids in articulating how to align the outcome of CE with the reasoning behind involving the public in the biobank governance process. The spectrum is useful in thinking about and planning CE, and hopefully will allow for clear delineation for biobanks seeking to introduce CE efforts in their internal governance process, as well as aid in guiding potential considerations

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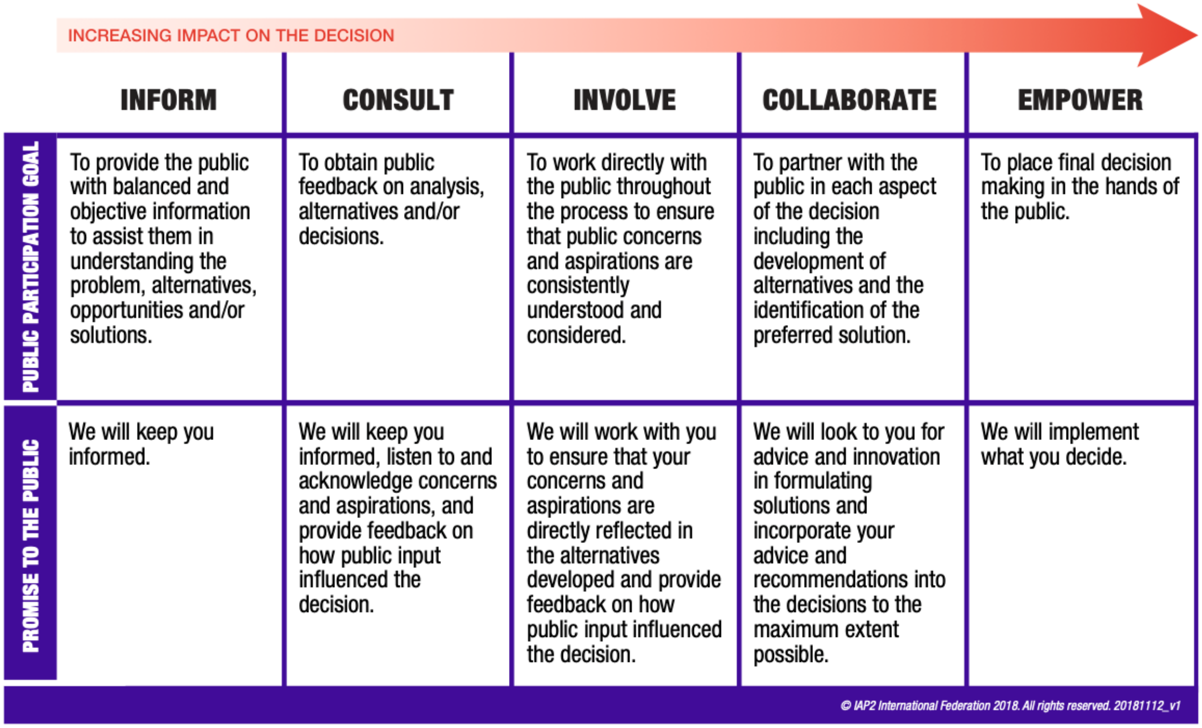
[1] In the context of this section of the thesis, 'international' is understood as countries from outside of North America, including the UK, New Zealand, the continent of Africa, Europe, etc.

they should incorporate into their approach. It also will allow for Canadian COVID-19 biobanks to identify the extent of the impact they seek with their choice to involve the community in the governance of their biobank.



INCREASING IMPACT ON THE DECISION

	INFORM	CONSULT	INVOLVE	COLLABORATE	EMPOWER
PUBLIC PARTICIPATION GOAL	To provide the public with balanced and objective information to assist them in understanding the problem, alternatives, opportunities and/or solutions.	To obtain public feedback on analysis, alternatives and/or decisions.	To work directly with the public throughout the process to ensure that public concerns and aspirations are consistently understood and considered.	To partner with the public in each aspect of the decision including the development of alternatives and the identification of the preferred solution.	To place final decision making in the hands of the public.
PROMISE TO THE PUBLIC	We will keep you informed.	We will keep you informed, listen to and acknowledge concerns and aspirations, and provide feedback on how public input influenced the decision.	We will work with you to ensure that your concerns and aspirations are directly reflected in the alternatives developed and provide feedback on how public input influenced the decision.	We will look to you for advice and innovation in formulating solutions and incorporate your advice and recommendations into the decisions to the maximum extent possible.	We will implement what you decide.

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Figure 3: International Association for Public Participation's (IAP2) Spectrum of Public Participation (2018)

In order to provide context to these CE strategies identified in my narrative review, I assess the strategies according to the IAP2 spectrum of public participation.[41] The spectrum is not a standard used by biobanks for CE, and there is no obligation for biobanks to employ spectrum in their work. Rather, I chose to use the IAP2 spectrum as a theoretical lens to interpret and orient the CE strategies in biobanking identified through my research. This spectrum can be used to help delineate the degree of public engagement for anything involving the public, including public health research; however, as public health research (and in particular biobank research) is the focus of this thesis, I will discuss the spectrum in the context of biobanking research. The IAP2 spectrum consists of 5 stages or goals which are used to delineate kinds of public engagement in public health research.

The first tier of the spectrum is 'inform', which is defined by IAP2 as providing "… the public with balanced and objective information to assist them in understanding the problem, alternatives and/or solutions," that is associated with whatever they are being informed of.[41] This is the lowest tier of the spectrum, and it serves to keep the public informed on a research project but does not provide any space to integrate the public or community in any decisional capacity. 'Inform' is a one-way type of information sharing, where researchers provide the community with information, but the community does not provide researchers with any information or input. Four of the total strategies (33) identified through my narrative review that fall into this category include public-facing educational videos and surveys (see: figure 4).

The second tier on the spectrum is 'Consult', which is defined by IAP2 as "[obtaining] public feedback on analysis, alternatives and/or decision".[41]This goal keeps the public informed (as is also achieved with the first tier), in addition to providing a space for community voices, and for researchers to incorporate community input into their research design. This is the most common kind of CE employed by institutions.[42] Most often, consultation allows community members the opportunity to comment on already-developed research plans and is a two-way mode of information sharing.[42] Critics of this CE approach argue that consultation can become tokenistic and does not provide communities a space to share their assessment of a research project or influence it in a meaningful capacity.[42] Thirteen of the total CE strategies identified in my review fall into this category (see: figure 4).

The third goal or tier of the spectrum is ‘involve’, wherein researchers “…work directly with the public throughout the process to ensure that public concerns and aspirations are consistently understood and considered”.[41] Here, researchers work with community groups to ensure that community goals become incorporated elements of the research design. At this tier, researchers should provide communities with feedback on how their input has influenced the research design. This goal represents a shift in both community voice and power, allowing for equal opportunity for researchers and communities to influence the shape that a research project takes. ‘Involve’ creates a space for communities to have a direct say on the research and decisions that impact them.[41] This represented 5 of the total strategies identified (see: figure 4).

The fourth goal or tier of the spectrum is ‘Collaborate’, which entails “…[partnering] with the public in each aspect of the decision including the development of alternative and the identification of the preferred solution”.[41] This tier delegates decisional power to the community, wherein researchers turn to the community for guidance and ‘innovation’ to create solutions to problems (IAP2, 2018). This stage creates a space to bring together unique strengths of community groups and researchers to build capacity and identify and address challenges that may not be noticed without collaboration. Importantly, IAP2 explains that at this tier, the ‘advice and recommendations’ of the community will be incorporated into a research project or design to “…the maximum extent possible”.[41] Fourteen total strategies identified in this review are considered collaboration (see: figure 4).

The fifth and final tier of the IAP2 spectrum of public participation is ‘empower’. IAP2 define this tier as placing “final decision-making in the hands of the public”.[41] Accordingly, the decisions made by a community will necessarily be implemented within a research project. Of note, the definition given by the IAP2 could be argued to not fully encompass the decisional capacity implied by ‘empower’. This definition implies that communities are being given decisional power by researchers or institutions. It is important to note that, often, community groups reach the ‘empower’ tier through advocacy work and grassroots campaigns, which seek improved capacity within a community, established by, and for, a community. This tier entails community ownership and ensures that communities have a decisional authority on the research design and expected outcomes. Often this degree of public participation targets equity gaps, encourages a collective vision for local community ownership, and builds infrastructure for future generations of community members.[42] One strategy identified through my narrative review on CE is considered as falling into this tier of public engagement (see: figure 4).

In addition to the above tiers, ‘Facilitating Power’ have adapted the spectrum to include a ‘tier 0’.[42] While this is not a part of the original IAP2 spectrum, tier 0, or ‘ignore’, is described by Facilitating Power as “[denying] access to the decision-making processes.” Importantly, they note that tier 0 represents the status quo in much research. This claim is made in consideration of the systematic marginalization of voices of vulnerable people with respect to public issues. Facilitating Power explains that to move beyond ‘ignore’, “concerted efforts” must be made to eliminate barriers preventing active engagement and participation of community groups”.[42] Facilitating Power adapted the spectrum for work done in public policy, and by consequence, tier 0 may be more of a concern for policy making in social sciences spaces.[42] However, it is valuable to consider how deciding not to address or acknowledge ‘community’ (whether a specific community or community in a more general sense) in biobank research is effectively ignoring that communities are implicitly impacted by such research.

2.4. Canadian COVID-19 Biobank Identification and Internal Governance Document Retrieval

The third and final methodological component of this thesis consists of a document retrieval and subsequent analysis of Canadian COVID-19 Biobank internal governing policies. In October 2021, I consulted the *Biobank Resource Centre,* developed by the Office of Biobank Education and the Canadian Tissue Repository Network.[43] The *Biobank Resource Centre* has a 'Biobank Locator' service, which I used to identify COVID-19 specific biobanks operating in Canada.[43] Using the locator tool, I conducted three keyword searches using the "Biobank Locator" search function, one with the keyword 'COVID,' which returned 10 biobanks, one with the keyword 'coronavirus', which yielded 1 additional biobank result, and one search with the keyword 'SARS-CoV-2' which yielded no new results.

This approach resulted in a total of 10 biobanks specific to COVID-19 operating in Canada (see: table 2). Where applicable, I consulted the websites of these biobanks to obtain information on their governance policies; however, not every biobank I identified has a website, nor information on their internal governance policies openly available on their websites. As such, if the biobanks did not have a website, or if their governance policies were not available online, I contacted biobank coordinators via email, according to their contact information provided by *Biobank Resource Centre.*[43] This approach resulted in communication with 8 of the 10 biobanks. Despite communicating with 8 of 10 biobanks, I was able to obtain only 2 documents relating to the internal governance of such biobanks (see: table 3)

After identifying primary sources, I undertook a content analysis of the internal governance documents of COVID-19 Biobanks to investigate their approaches to CE. Content analysis is a qualitative research approach used to elicit themes and concepts from qualitative data.[44] This approach is most useful for researchers who seek to use inference to draw conclusion from texts.[44] Accordingly, content analysis was chosen for this thesis to assess the CE sections of biobank internal governance policies. Often, content analysis will entail coding data from a given collection of primary texts.[44] With respect to this thesis, a small number of primary texts were retrieved, and it was therefore considered not necessary to develop a codebook, as the amount of primary source material was not significant enough to justify coding the data.

Table 2: Canadian COVID-19 Biobanks identified and availability of their internal governance documents

Name of Biobank	Province Biobank is Located	Type of document	Governance document(s) available online	Access
ARBS CORONA II, Canada	British Columbia	N/A	No	Unable to retrieve governance policy
BC COVID-19 Biobank Network Canada	British Columbia	Governance Framework	No	Yes
BQC19 Biobank	Quebec	Management Framework	Yes	Yes
COVID-19 BioBank	Ontario	N/A	No	Unable to retrieve governance policy
Hamilton COVID-19 Biorepository	Ontario	N/A	No	Unable to retrieve governance policy
ICCN/PCRC Biobank	British Columbia	N/A	No	Unable to retrieve governance policy

Island Health COVID-19 Biobank	British Columbia	N/A	No	Unable to retrieve governance policy
RESPONSE	British Columbia	N/A	No	Unable to retrieve governance policy
Response Maternal-Infant Clinical and Biospecimen Access Platform	British Columbia	N/A	No	Unable to retrieve governance policy
UHN COVID-19 Biobank	Ontario	N/A	No	Unable to retrieve governance policy

Chapter 3: Results

3.1. Literature Review

Database searches for literature on the topic of COVID-19 biobank governance resulted in a total of 14 articles for full-text review. Following full-text review, 8 articles were found to meet the inclusion and exclusion criteria of this review. During the screening process, articles were primarily excluded for not relating to COVID-19 biobanks, specifically, or for not relating to the good governance of such biobanks. Results from the literature review of COVID-19 and biobank governance are found in the introduction section of this thesis (section 1.3). This review resulted in 6 overarching themes: (1) Biobanking as a Public Health Response to the Pandemic; (2) Time Pressures and Access to COVID-19 biosamples; (3) Challenges with Guidance/ Lack of Pandemic-Preparedness Governance Guidelines; (4) Biosafety; (5); and, (6) CE. The literature review demonstrated that while CE was a topic of interest for some biobanking experts, the concern of experts was largely focused on regulatory challenges relating to the impact of the lack of preparedness and guidelines to direct biobanking during a public health emergency. This played a role in motivating my scope of inquiry in order to supplement the relative lack of guidance and consideration into the value of CE during public health crises such as COVID-19, and also the value of developing downstream CE strategies for COVID-19 biobanks.

3.2. Normative Guidelines results

I identified a total of 8 normative documents stemming from 8 distinct organizations for the normative document review portion of this thesis. A total of 5 documents offered guidance specifically for biobanks, while 3 documents were more general in their scope, providing guidance for the conduct of human health research. Normative documents were identified through Google Advanced searches as well as reference screening of a key text.[38] A total of 4 of the included normative documents are developed by Canadian organizations, while 4 of the documents are directed towards the international biobanking community. One of the documents was returned from McGill University, which is the institution of study at which this thesis is undertaken. As described in the methods, I used Google Advanced to identify normative documents. It is therefore possible that the location at the time of the search had an influence on the results returned, and possible that not all normative documents for biobanking were captured in my search.

Normative documents were decided as a valuable resource for this thesis, as they are public-facing guidance documents. It was inferred that biobankers would be more likely to turn to normative documents for guidance when creating biobanks, or when faced with public health emergencies such as COVID-19. Consulting normative guidance should therefore provide valuable additional context to my assessment of Canadian COVID-19 biobanks' internal governance documents. Table 3 provides a summary of the guidance of the normative documents included in this thesis, with respect to their commentary regarding CE in biobanking and biobank research.

I organized the results according to the extent of guidance provided, the context of scope, justification for CE, and the Canadian context. I chose to present the information in such a way to distill similar points between normative documents, and to demonstrate where the documents agreed and where they varied on the topic at hand. In addition, as this thesis is specific to Canadian COVID-19 biobanks and CE, it seemed prudent to devote attention to the Canadian context and the discussion seen within Canadian regulatory documents.

3.2.1. Extent of Guidance Provided

The scope of guidance provided by normative documents on CE varied greatly between organizations. Of the ten documents, all but the International Organization of Standardization discussed CE either directly in the context of biobanking, or in the context of human health research. Additionally, the Fonds de Recherche du Quebec provided minimal commentary on the role of CE in biobanking (see: table 3).[45]

Most of the normative documents expressed that biobanks should consult with relevant community groups and stakeholders. Organizations such as the CIOMS, P3G, WMA and IARC note that CE strategies should occur before the biobank or research projects begin to take shape.[12,46–48] Accordingly, early engagement allows community groups to have a say in the development of a biobank and have a direct say on associated research projects before samples are collected. The recommendation that biobanks should engage with communities before establishing a biobank also effectively incorporates research ethics boards in the process of ensuring that CE practices are employed by biobanks. This is due to the regulatory and governance role played by REBs, who assess research proposals for their scientific and social merit and identify potential ethical contentions associated with research projects. Biobanks are obligated to submit their internal governance frameworks to REBs for review before they are approved, and due to this role, REBs could provide an additional regulatory role to ensure that CE efforts follow the recommendations of organizations like the CIOMS, IARC, and P3G.[12,46,47]

Not all documents expressed that CE should begin at the outset of a project; however, there is a consensus that CE requires due consideration at the planning stage of a biobank. Organizations like the OCED and CIOMS remark that biobanks should have clearly delineated plans with respect to their benefit sharing approach.[46,49] Decisions relating to benefit sharing may entail passive CE, insofar as benefit sharing involves defining benefit for stakeholders within a biobank, and stakeholders in a biobank necessarily involve the community, to varying degrees.[49,50] Similarly, the TCPS-2 notes that CE can entail a range of strategies, such as "active participation and collaboration, to empowerment and shared leadership...".[11]

3.2.2. Context of Scope

Normative documents provided commentary to help define the scope and application of CE in the context of biobanking. One possible challenge that biobankers may face when seeking to implement CE in their governance strategies is delineating or defining 'community' within the context of their biobank. While this may be less of a challenge for disease-specific biobanks, 'community' may be less clear with respect to population-specific biobanks, which collect samples from donors who do not necessarily share a community identity. However, disease-specific biobanks do not always consist of a clearly delineated or identifiable community, as is the case with COVID-19 biobanks. COVID-19 biobanks are indeed disease-specific but often consist of samples from indeterminate or difficult to delineate community groups. Normative documents like the CIOMS's 'International Ethical Guidelines for Health-Related Research Involving Humans' provide insight into this challenge, noting that:

> …a community consists not only of people living in the geographic area where research is to be carried out; it also comprises different sectors of society that have a stake in the proposed research, as well as sub-populations from which research participants will be recruited…[46]

Therefore, biobanks should not only take care to determine the extent of their CE strategies at the beginning of their lifecycle but also should invest time into defining or delineating 'community' in the context of their biobank and research activities. This can be achieved per the CIOMS' recommendation by identifying who has a stake in the research, which may result in a broad definition of the community of interest and consider what could be understood as 'sub-population' community groups within the biobank.[46]

3.2.3. Justification for Community Engagement

The most common justifications for CE offered by the normative documents were that involving the community in health research as an opportunity to benefit both the community and biobanks and that CE facilitates public trust in the research enterprise. This argument was seen with most organizations, including the IARC, CIOMS, WHO, McGill University, OCED, and the Interagency Panel on Research Ethics.[11,12,46,49,51,52] Similarly, the CIOMS comments that CE can also help to reduce the social harms that may stem from research, such as the stigmatization of community groups.[46] The CIOMS notes that CE helps to improve ethical and social values and helps promote the successful conduct of research.

Similarly, it was noted that biobanks require the support of the public to operate, and maintaining a positive public perception of a biobank is a 'crucial consideration in the governance of a biobank'.[47] CIOMS notes that having an active and prolonged engagement with the community is a way to ensure that the impact of research is positive for communities and ensures the ethical and social value of research projects.[46] CIOMS also notes that CE is "critical" for facilitating trust between the community and researchers, and participants. The differentiation of participants and community in this context leads to the conclusion that these groups are not necessarily the same, and therefore biobanks may need to engage beyond the group of participants involved in a biobank to fulfill these recommendations given by normative documents with respect to CE.[46]

3.2.3. Canadian Context

Most documents specific or applicable to the Canadian or Quebecois context were largely consistent with the consensus seen with international documents. The TCPS-2 and international documents agreed on the implicit value of CE in public health research, the stage at which CE should occur during the lifecycle of a biobank (before public health research begins is established), and that CE improves transparency and public trust in the research enterprise.[11]

The Tri-Council Policy Statement is the foremost ethical guidance in Canada.[11] This document is used to guide the ethical conduct of research within the Canadian context and serves a prescriptive role for researchers and Research Ethics Board review. All individuals conducting research in Canada must demonstrate their understanding and complete TCPS-2 training in order to be able to conduct research in Canada.[11] Of note, the TCPS-2 restricts discussion of CE to Chapter 9 of the Tri-Council Policy Statement. This chapter is directed towards Indigenous, First Nations, Metis, and Inuit communities in Canada. The chapter acknowledges that CE is a process to "establish an interaction between a researcher (or a research team) and [an] Indigenous community…"[11] As the TCPS is a federal document to offer guidance for research taking place in Canada, this may explain why CE efforts in Canadian COVID-19 biobanks is somewhat skeletal. The TCPS, which provides ethical and normative guidance for not only researchers but Research Ethics Boards, does not stipulate expectations for CE outside of the scope of Indigenous Communities.[11] While chapter 9 of the TCPS is an important step forward in ensuring Indigenous solidarity in research and improving the ethical treatment of Indigenous peoples in Canada, its scope could be argued to be too limited to require or regulate CE outside of the context of research involving Indigenous peoples.

Table 3: Normative Guidance for the management of Community Engagement Committees

Institution	**Document**	**Guidance**
Council for International Organization of Medical Sciences[46]	International Ethical Guidelines for Health-Related Research Involving Humans (2016)	• From the inception of research planning, ensure full participation of communities in all steps of the project, including discussions of the relevance of the research for the community, its risks, and potential individual benefits, and how any successful products and possible financial gain will be distributed, for example through a benefit-sharing agreement. • This consultation should be an open, collaborative process that involves a wide variety of participants, including community advisory boards, community representatives, and members of the population from which research participants will be recruited. Research ethics committees should require community members to disclose any conflicts of interests (see Guideline 25 – Conflicts of interest). Active community involvement helps to ensure the ethical and scientific quality and successful completion of proposed research. In addition, it helps the research team to understand and appreciate the research context, promotes smooth study functioning, contributes to the community's capacity to understand the research process, enables members to raise questions or concerns, and helps to build trust between the community and researchers • **General considerations.** Proactive and sustained engagement with the communities from which participants will be invited to participate is a way of showing respect for them and the traditions and norms that they share. Community engagement is also valuable for the contribution it can make to the successful conduct of research. Community engagement is a means of ensuring the relevance of proposed research to the affected community, as well as its acceptance by the community. In addition, active community involvement helps to ensure the ethical and social value and outcome of proposed research. Community engagement is especially

		important when the research involves minorities or marginalized groups, including persons with stigmatizing diseases such as HIV, to address any potential discrimination. • **A community consists not only of people living in the geographic area where research is to be carried out; it also comprises different sectors of society that have a stake in the proposed research, as well as sub-populations from which research participants will be recruited.** Stakeholders are individuals, groups, organizations, government bodies, or any others who can influence or are affected by the conduct or outcome of the research project. The process must be fully collaborative and transparent, involving a wide variety of participants, including patients and consumer organizations, community leaders and representatives, relevant NGOs and advocacy groups, regulatory authorities, government agencies and community advisory boards. Also, it is important to ensure diversity of views within the consultation process. For instance, when community leaders are men only, researchers should actively include the views of women, as well. There may also be value in consulting individuals who have previously participated in comparable studies. • The research protocol or other **documents submitted to the research ethics committee should include a description of the plan for community engagement,** and identify resources allocated for the proposed activities. This documentation must specify what has been and will be done, when and by whom, to ensure that the community is clearly defined and can be proactively engaged throughout the research to ensure that it is relevant to the community and is accepted. The community should participate, when feasible, in the actual discussion and preparation of the research protocol and documents. • Researchers, sponsors, health authorities and relevant institutions should take care that **community engagement does not lead to**

		pressure or undue influence on individual community members to participate (see commentary on Guideline 9 – Individuals capable of giving informed consent, section on Dependent relationship). To avoid such pressure, individual informed consent must always be sought by the researcher. • **Researchers and research ethics committees** should be cognizant of the point at which the process of community engagement becomes a stage of formative research that itself requires ethics review. Examples of community engagement processes that may require ethics review include systematic data collection that can be generalized and disseminated in forums outside of the community in which they were implemented, as well as any data generation that could create social risks for participants. • **Engagement at the earliest opportunity.** Before a study is initiated, the community from which participants will be recruited should, when feasible, be consulted about their research priorities, preferred trial designs, willingness to be involved in the preparation and conduct of the study. Engaging the community at the earliest stage promotes smooth study functioning and contributes to the community's capacity to understand the research process. Community members should be encouraged to raise any concerns they may have at the outset and as the research proceeds. Failure to engage the community can compromise the social value of the research, as well as threaten the recruitment and retention of participants. • **Community engagement should be an ongoing process**, with an established forum for communication between researchers and community members. This forum can facilitate the creation of educational materials, planning the necessary logistical arrangements for the conduct of the research, and providing information about the health beliefs, cultural norms, and practices of the community. Active engagement with community members is a mutually educative

		process, which both enables researchers to learn about communities' cultures and understanding of research- related concepts and contributes to research literacy by educating the community about key concepts critical for understanding the purpose and procedures of the research. Good-quality community engagement helps to ensure that existing community dynamics and power inequities are not allowed to derail the process of ensuring the comprehensive engagement of all relevant community stakeholders. Care should be taken to solicit the views of all sectors of the community proactively and sensitively. Community members should be invited to assist in the development of the informed consent process and documents to ensure that they are understandable and appropriate for potential participants. • **Confidence and trust.** Engaging the community strengthens local ownership of the research and builds confidence in the ability of leaders to negotiate various aspects of the research, such as recruitment strategies, care for the health needs of study participants, site selection, data collection and sharing, ancillary care and post-trial availability of any developed interventions for populations and communities (see Guideline 2 – Research conducted in low-resource settings, and Guideline 6 – Caring for participants' health needs). An open and active process of community engagement is critical for building and maintaining trust among researchers, participants, and other members of the local community. An illustration of successful involvement of the community was a study in the Eliminate Dengue Program in Queensland, Australia. Previous introductions of genetically modified strategies for dengue vector control had generated international controversy by inadequately engaging host communities. This successful episode used well-established techniques in social science to understand the community's concerns and gain their support for conducting the trial.

		• **Roles and responsibilities.** Any disagreements that may arise regarding the design or conduct of the research must be subject to negotiation between community leaders and the researchers. The process must ensure that all voices are heard, and that pressure is not exerted by community members or groups with greater power or authority. In cases of irreconcilable differences between the community and researchers, it is important to specify in advance who will have the final say. The community must not be permitted to insist on including or omitting certain procedures that could threaten the scientific validity of the research. At the same time, the research team must be sensitive to cultural norms of communities to support collaborative partnerships, preserve trust, and ensure relevance. The value of beginning community involvement at the earliest opportunity is that any such disagreements can be aired, and if unable to be resolved, the research may have to be forgone (see Guideline 8 – Collaborative partnership and capacity-building for research and research review). If a research ethics committee is confronted with a severe split in the community about the design or conduct of a proposed study, the committee should urge the researchers to conduct the study in another community. • **Engagement by communities or groups.** In some cases, communities, or groups themselves initiate or conduct research projects. For example, patients with rare diseases may connect on online platforms and decide to collectively alter their treatment regimen while documenting the resulting clinical effects. Researchers should engage with these initiatives, which can offer valuable insights into their own work.
IARC[12]	Recommendations for Biobanks: Section 3 (2018)	• **Good governance includes engaging with the public** during the establishment of a biobank and throughout the life cycle of the biobank.

		• **This committee could help biobank personnel and associated researchers to better understand public opinion.** • For some larger biobanks, **advisory panels of study participants meet regularly and provide feedback** on new projects and review study materials, newsletters, and questionnaires.
Policy Partnership Project for Genomic Governance[47]	P3G Model Framework for Biobank Governance (2013)	• During the "before" period of a biobank, **planning design and creation** - at this stage in the process these must be discussion with funders, an examination of applicable laws and regulations and public engagement • **A biobank cannot operate without social acceptance.** Public perception is now seen as a crucial consideration in the governance of a biobank • **Transparency and accountability of the biobank ensure positive public perception**, enhancing the legitimacy and trust in the biobank • Public engagement committees help researchers **gauge the public's acceptance or concerns with the biobank,** enabling researchers to design their studies accordingly. This input fosters legitimacy and **sustainability** to the resources. • Public engagement encapsulates public perspective… may remain an external governance mechanism even prior to recruitment, • **public engagement can take various forms** depending on the context and culture of the targeted country or population, including forums, citizen conferences, town hall meetings, surveys, and committees. • There is a need for both the launching and **ongoing public support and engagement for the proper governance of population biobanks.**
Fonds de la Recherche en	Governance Framework for Data	• Document questions if the public should be told how data banks are used, and if so, how?

Santé du Québec[45]	Banks and Biobanks (2006)	
McGill University[52]	Guidelines for biobanks and Associated Databases (2015)	• To ensure that they are governed by the overarching principles of transparency and accountability, **Biobanks and associated Databases should clearly define their mission, operational scope, Governance structure and managerial responsibilities**. This information **should be public.**
Interagency Panel on Research Ethics[11]	Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (2018)	• Ch. 9.a. Community engagement – is a process that **establishes an interaction between a researcher (or a research team) and the Indigenous community** relevant to the research project. • …**signifies the intent of forming a collaborative relationship between researchers and communities,** although the degree of collaboration may vary depending on the community context and the nature of the research. • …**engagement may take many forms including** review and approval from formal leadership to conduct research in the community, joint planning with a responsible agency, commitment to a partnership formalized in a research agreement, or dialogue with an advisory group expert in the customs governing the knowledge being sought. • …**may range from information sharing to active participation and collaboration,** to empowerment and shared leadership of the research project. • **Communities may also choose not to engage actively** in a research project, but simply to acknowledge it and register no objection to it.
OCED[49]	OCED Guidelines on Human Biobanks and Genetic Research Databases (2018)	• 9.1. The operators of the Human Biobanks and Genetic Research Databases (HBGRD)…**should have a clearly articulated policy regarding benefit sharing….** • policy **should** address, inter alia, whether tests or products arising from research using its **resources might be shared with the**

		community and/or the general population, and how such sharing will be affected. - Research pertaining to a portion of a population, especially amongst those sharing **common characteristics, may raise issues of potential discrimination and stigmatisation**. For example, an association between a specific heritage and a particular disease may lead to discrimination from insurers or employers - **HBGRD should make information publicly available about the possibility** that research results generated from population-based human genetic data may have repercussions for individuals, participants, their family, groups to which they belong and the community. **Examples of repercussions may include loss of dignity or community stigmatisation.**
World Medical Association[48]	Declaration of Taipei on ethical considerations regarding health databases and biobanks (2016)	- **To foster trustworthiness,** Health Databases and Biobanks must be governed by internal and external mechanisms based on the following principles: - **Protection of individuals:** Governance should be designed so the rights of individuals prevail over the interests of other stakeholders and science; - **Transparency:** any relevant information on Health Databases and Biobanks must be made available to the public - **Participation and inclusion:** Custodians of Health Databases and Biobanks must consult and engage with individuals and their communities. - **Accountability:** Custodians of Health Databases and Biobanks must be accessible and responsive to all stakeholders.

3.3. Pre-COVID-19 Biobank Community Engagement Strategies

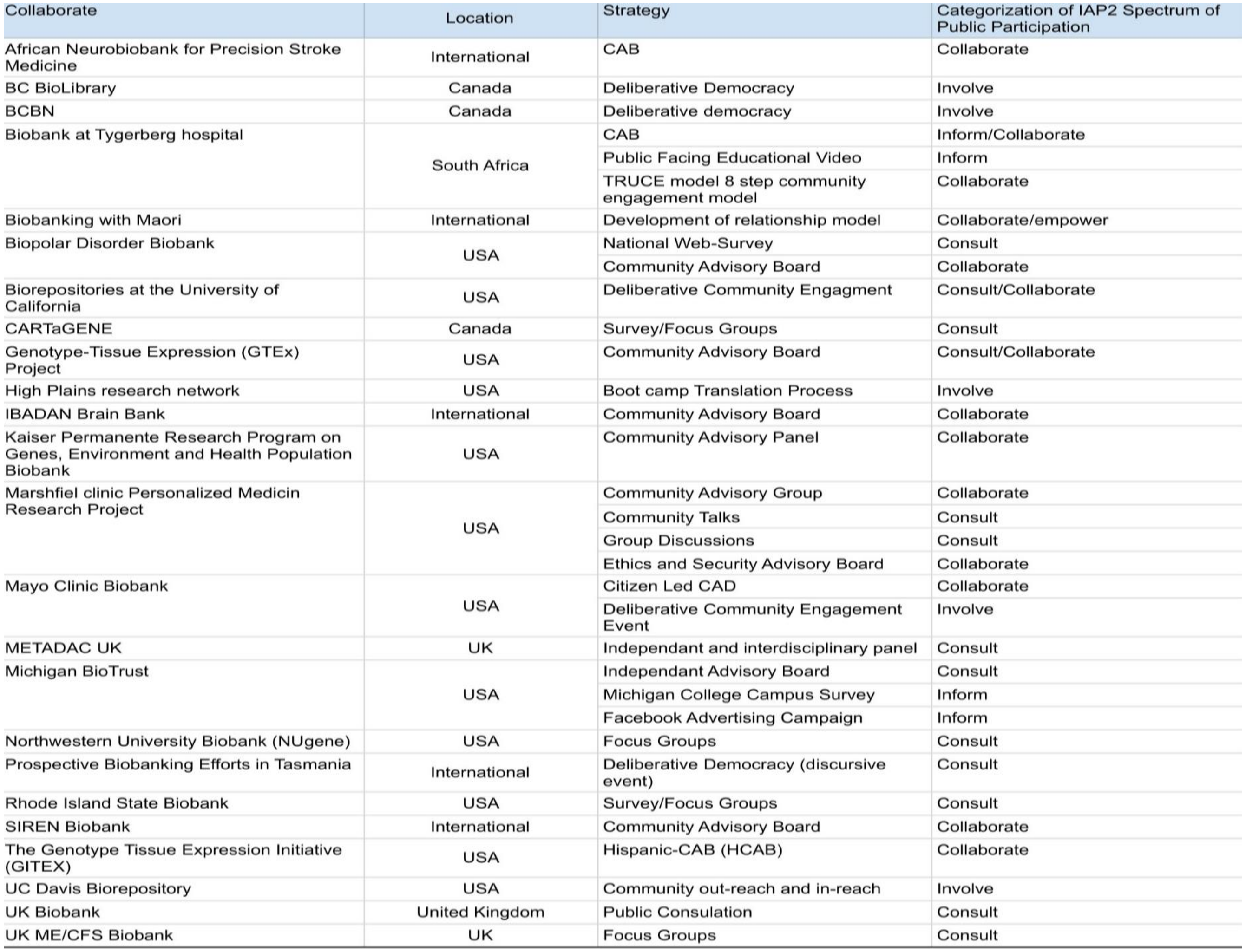
The primary goal of this section was to contribute to my objective of identifying the scope of CE available to biobanks and use that information to contribute to my analysis of Canadian COVID-19 Biobank governance policies. The first step to understanding the scope of CE employed by biobanks was identifying articles discussing CE strategies and extracting the documents. I identified a total of 282 articles on the topic of biobanking and CE using the approach described in the methods section of this thesis. Of those articles, I excluded 177 that did not meet the inclusion criteria of my search. Most commonly, articles were excluded either because the articles were theorizing or offering hypothetical solutions for biobank engagement, or because they did not involve community groups. I also excluded articles if the described CE strategy was not done by a human health biobank. This review resulted in 25 articles for full-text review and extraction, and a total of 33 CE strategies employed by 24 distinct biobanks or biobanking initiatives were identified by my search (see: figure 4).

Once I extracted these articles, I organized CE strategies according to the name, or best available name, of the biobank employing such efforts. I say 'best available name' because some of the biobanks were not named but tied to an institution. For example, one of the highlighted international examples is concerning the biobanks at Tygerberg Hospital in South Africa, so I refer to this collectively as 'biobanking at Tygerberg Hospital'.[53] I then iteratively sorted the biobank CE examples according to how I interpreted them to lie on the spectrum of public engagement. I acknowledge that there is an opportunity for bias with respect to how I categorized these strategies. However, to minimize bias, I ensured that strategies were sorted according to the best-fitting definition given by the IAP2. As a result, there are instances where strategies have the same title (i.e., community advisory board) but are not sorted into the same

IAP2 goal. This is because while they have the strategies share a title, their approaches varied significantly enough that warranted sorting them into different categories (See: figure 4). Regardless, it should be noted that these strategies were categorized by one person (i.e., without external validation). In addition, the strategies may be more complex or involved than what is explained in the article I identify them from. As well, further CE may have since occurred that was not captured in my scope. As such, while I have taken steps to ensure that my assessment is as unbiased, critical, and accurate as possible, it should be noted that my summaries may not paint a complete picture of all such CE strategies.

Strategies identified through my search include community talk events, community out/in-reach events, translation events, education videos, focus groups, ethics and security advisory board, community advisory boards, panels, and groups, and deliberative democracy/discursive events. The next section of this thesis will provide a summary of selected strategies as described in the article or articles from which they were identified.

Figure 4: Community Engagement Strategies identified via narrative review



Collaborate	Location	Strategy	Categorization of IAP2 Spectrum of Public Participation
African Neurobiobank for Precision Stroke Medicine	International	CAB	Collaborate
BC BioLibrary	Canada	Deliberative Democracy	Involve
BCBN	Canada	Deliberative democracy	Involve
Biobank at Tygerberg hospital	South Africa	CAB	Inform/Collaborate
		Public Facing Educational Video	Inform
		TRUCE model 8 step community engagement model	Collaborate
Biobanking with Maori	International	Development of relationship model	Collaborate/empower
Biopolar Disorder Biobank	USA	National Web-Survey	Consult
		Community Advisory Board	Collaborate
Biorepositories at the University of California	USA	Deliberative Community Engagment	Consult/Collaborate
CARTaGENE	Canada	Survey/Focus Groups	Consult
Genotype-Tissue Expression (GTEx) Project	USA	Community Advisory Board	Consult/Collaborate
High Plains research network	USA	Boot camp Translation Process	Involve
IBADAN Brain Bank	International	Community Advisory Board	Collaborate
Kaiser Permanente Research Program on Genes, Environment and Health Population Biobank	USA	Community Advisory Panel	Collaborate
Marshfiel clinic Personalized Medicin Research Project	USA	Community Advisory Group	Collaborate
		Community Talks	Consult
		Group Discussions	Consult
		Ethics and Security Advisory Board	Collaborate
Mayo Clinic Biobank	USA	Citizen Led CAD	Collaborate
		Deliberative Community Engagement Event	Involve
METADAC UK	UK	Independant and interdisciplinary panel	Consult
Michigan BioTrust	USA	Independant Advisory Board	Consult
		Michigan College Campus Survey	Inform
		Facebook Advertising Campaign	Inform
Northwestern University Biobank (NUgene)	USA	Focus Groups	Consult
Prospective Biobanking Efforts in Tasmania	International	Deliberative Democracy (discursive event)	Consult
Rhode Island State Biobank	USA	Survey/Focus Groups	Consult
SIREN Biobank	International	Community Advisory Board	Collaborate
The Genotype Tissue Expression Initiative (GITEX)	USA	Hispanic-CAB (HCAB)	Collaborate
UC Davis Biorepository	USA	Community out-reach and in-reach	Involve
UK Biobank	United Kingdom	Public Consulation	Consult
UK ME/CFS Biobank	UK	Focus Groups	Consult

See: [16,37,52,54–56,58–60,60–67,68]

3.4.1. Example strategies for Biobank Community Engagement

The following section provides summaries of CE strategies from the USA, outside of North America (i.e., ‘international’), and within Canada. The structure of the summaries is modelled on Lemke and colleagues’ approach to highlighting biobank CE in their text “Community engagement in biobanks: experiences from the eMERGE network”.[39] I identified a large number of examples of CE through this narrative literature review. Due to the sheer volume of results, I chose to highlight 2 selected examples each of Canadian, American, and international approaches to CE and biobank governance. The examples were chosen deliberatively to highlight the scope of examples, and demonstrate the success and challenges experienced by biobanks conducting CE. It should be noted that my search revealed only two Canadian examples, which are at times similar to other chosen examples. I conclude each strategy example with an assessment of the strategy within the context of IAP2s spectrum for CE.

3.4.1.1. USA – Selected Examples

1.) The UC Davis biorepository – Community out-reach and in-reach:[2]

As part of an initiative with the Asian American Cancer Education Study (AACES) community out-reach and in-reach events were held to increase the number of available biospecimens for cancer research with Asian Americans in California.[68] Previous studies conducted as part of the AACES found that Asian Americans had limited awareness on

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[2] Described in Dang and Chen, 2018

biobanking, but an increased knowledge on biobanking within the community was shown to correlate with a higher willingness to donate samples within the community.[68] To expand upon these results, researchers with the AACES conducted multiple CE events to encourage increased sample donation to the biobank research among the Asian American community. These CE events involved conducting community out-reach and community education on the topic of biobanking and its associated benefits, and then holding a community blood drive to provide further education to blood donors on biobanking, and to encourage donation to the UC Davis Biorepository. These events were done with the goal of improving health research and knowledge of cancer within the Asian American Community.[68]

During the blood drive out-reach event, health educators engaged potential participants (who came to donate blood for the drive) on the topic of also donating blood to the UC Davis biorepository. Participants were able to agree to donate to the bank in that moment, were consented, and blood was drawn and subsequently donated to the UC Davis Biorepository. This blood drive CE strategy resulted in 1127 blood specimens for cancer research over the course of 10 blood drives.[68] Dang and Chen indicate that this collection entails "...one of the largest numbers of blood biospecimens from Asian Americans for cancer research..." known of at the time of writing.[68] Dang and Chen cite community-level education initiatives (community in-reach) and overall improved community trust for the success of these blood drives in improving the capacity of Asian American biosamples for biobank research.

The authors acknowledge that trust is integral in improving health disparities and note that they conducted a decade of community partnership to improve trust and encouraged transparency between the community and the researchers. Similarly, they note that mistrust poses a "significant barrier to engaging diverse communities in biospecimen donation".[68] Given the success of the event, the authors encourage collaborating with community organizations and local community groups., noting that this event was made possible by over a decade of working with local community groups to form partnerships, and trust in the biobank was continued through transparency about its efforts to donors.

I have classified this CE as both ‘consult’ and ‘collaborate’. In conducting community in-reach events, the AACES provided a space for education, both of community members and for researchers, to better understand the perspective of the Asian American community on the topic of biobanking. The in-reach events helped to harmonize the interests of local community groups with the goal of improving health outcomes in the Asian American community.[68] As such, the in-reach events seem to best entail collaboration; community goals and needs were identified directly as a result of the relationship established with local community groups, which then helped to ensure that the out-reach events were culturally relevant and contributed to the existing legacy of trust between the Asian American community, the AACES researchers, and local community groups. This collaboration, in tandem with informing participants of the biobank and the value of contributing to biobanks for public health research, entails a clear success, given the number of samples via the blood drive. This example demonstrates that multiple approaches to CE not only can occur contiguously (and perhaps should), but that different CE efforts have different and valuable outcomes associated with them.

2.) Mayo Clinic Biobank – Deliberative Democracy Event, Citizen Led Community Advisory Board, and Community Newsletter/Blog:[3]

The Mayo Clinic is a seminal example of biobanking CE in the United States. The Mayo Clinic Biobank is a population-biobank and has donors stemming from the multiple Mayo Clinic locations (Minnesota, Florida and Arizona) as well as Mayo Clinic patients who come to the clinic from all over the world.[39] Since 2007, when it conducted a 'deliberative democracy event', the Mayo Clinic has employed a number of extensive CE strategies, including establishing a CAB. The first deliberative democracy event was done upstream of the creation of the biobank to offer space for the community to influence its development and governance. Accordingly, CE has played a governance role for the Mayo Clinic biobank since is inception. I will proceed by providing a summary of the Mayo Clinic's CE identified via multiple documents from my narrative review.

To conduct the deliberative democracy event, 20 lay members of the Olmsted Country in Minnesota were selected to attend.[54] Community members were chosen such that they varied according to their age, sex, social and economic status, race, ethnicity, and employment status.[54] Participants met in groups, and the discussion was guided by professional facilitators to aid in documenting and developing the community recommendations.[54] The community members made recommendations about biobank procedures. Some examples of their recommendations include developing a set of guiding principles on data sharing, policies on the return of individual

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[3] Described in Lemke *et al.*, 2010; Olsen *et al.*, 2014; Olsen *et al.*, 2019

or collective research results, and planning for long-term community oversight.[39] The event also greatly influenced the form and structure of the Mayo Clinic's biobank ICF; community members' insight was integral in ensuring that the ICF was openly communicative, simple, and brief. The members also helped to develop a policy that the first, and all future ICFs, are developed in tandem with insight from the biobank's CAB.[39] Accordingly, one key and longstanding outcome of this deliberative CE event was the recommendation that Mayo Clinic establish a biobank CAB.[39]

After the democracy event, half the participants agreed to become CAB members for the Mayo Clinic Minnesota CAB.[54] The Mayo Clinic has since developed CABs for each of its locations in Florida, Arizona, in addition to Minnesota.[55] The CABs consist of members chosen to reflect the diversity of community interests, and the backgrounds of samples stored in the bank.[55] The CAB members meet regularly to review research protocols and serve the role of representing the community and promoting community-engaged research in the bank.[55] The recommendations of the advisory board are not binding, but they are often incorporated into policies and decisions.[39] The CABs are co-chaired by each of the Mayo Clinics' Biomedical Ethics Programme Director and a community member who is elected by the CAB members.[39] The co-chairs are active voting members of the biospecimen trust oversight group and access committees.[39] The board has contributed to shaping policy on topics such as incidental findings, and practices for engaging with potential research participants. One unique role of the CAB is that it works in collaboration with a biobank access committee to develop a policy for determining when results of the Mayo Clinic's bank warrant being told or offered to participants.[39] The CAB and access committee developed a process to assess potentially clinically meaningful results, which involves review by an ad hoc panel of experts to determine the extent that the research results could affect the clinical care of biobank participants.[39] Other initiatives stemming from the CABs and the deliberative democracy event also led to a community newsletter, a website, and a blog, to keep participants and community members informed on the bank.[39]

The Mayo Clinic is a key example of CE in biobanking in the US and can be looked to by the international biobank community as a set of robust CE strategies. The Mayo Clinic offers another example of multiple CE events taking place in the context of a single bank; however, this context more explicitly demonstrates the involvement of CE in the context of biobank governance. I have categorized activities like the deliberative democracy event as 'involve' insofar as this event impacted the development of the CAB, which allowed for collaborative decision-making for the governance decisions relating to the bank, such as return of individual research findings. This example demonstrates that involving the public at different stages on the spectrum can lead to additional CE at the next, or future, stage of a biobank. The community newsletter and blog is best categorized as 'informing'; however, it is important to consider that CAB members exist to represent the interest of the community of donors and it is a continuation of creating a dialogue of transparency between the biobank and the community. These efforts together have allowed for a robust network of CE that have become integral to the conduct and governance of the biobank.

3.4.1.2. International – Selected Examples

1) He Tangata Kei Tua Relationship Model for Maori biobanking:

In their article, Beaton and colleagues describe the CE conducted with Maori, the Indigenous peoples of New Zealand (Aotearoa) which led to the creation of the 'He Tangata Kei

Tua Relationship Model for Maori Biobanking'.[56] As biobanks are becoming increasingly more common worldwide, the Te Mata Ira Research Council of New Zealand funded a project to develop a set of best practices and ethical guidelines for genomics research with Maori.[56] The outcome of this CE approach was a document written to describe ethical conduct for any current and future biobanking done with Maori. This was achieved through a multitude of methods, including literature reviews, interviews, tribal meetings (iwi hui), and workshops.[56] The literature review, workshops, and tribal meetings were done to understand the perspectives and perceived impacts of biobanking for Maori, and the results were used to inform the development of the 'He Tangata Kei Tua Relationship Model for Maori biobanking'.[56,69]

The community consultation preceding the document placed emphasis on identifying "culturally significant concepts."[56] The authors discuss that biological samples such as DNA, and the data that stems from such samples, are considered 'tapu' or sacred to the Maori, which means that it is subject to certain cultural provisions.[56] Accordingly, the CE events indicate that Maori genomic data should be monitored by cultural stewards. In addition, research protocols involving Maori genomic tissue are expected to "address physical and spiritual components of consent".[56] The authors explain that the use of Maori Genomic data for research purposes requires ensuring that the research is culturally educated.

Another important conclusion from the development of the relationship model is that the scope and specificity of consent are key to Maori.[56] While many, if not most, biobanks will follow a broad consent model (therefore allowing for future use of biosamples without obtaining consent from participants each time), the results of this CE with the Maori indicates that Maori had a "preference for 'consent for every use.'"[56] There are also expectations that tribal groups (iwi) are consulted for the purpose of gaining collective community consent. The CE also entailed developing provisions for unethical researcher behaviour by encouraging the use of research contracts or partnership agreements between Maori and researchers.

The authors note that in terms of bolstering future CE efforts, researchers should work to form long-standing relationships with Maori to ensure their accountability and form an avenue for feedback and communication.[56] In addition, the samples collected for biobanking should not be used outside of the explicit context of the consent given, and communities should be consulted before data is reused for secondary research studies. In addition, the authors explain that Maori should be given individual research results, and special focus should be given to knowledge translation such that the results from genomic research are relevant to the community, and that clinically actionable results are shared with service providers to ensure explicit Maori benefits.

The He Tangata Kei Tua model, which articulates these community expectations and the results of the CE discussed above, is an effort to develop culturally acceptable policies for biobanking and genomic research with Maori.[56] The ensuing relationship model is likely best categorized as 'collaborate'. The development of this document looks rather different that some of the other CE examples discussed in this thesis. However, it is a similar to documents that can be found with other Indigenous community groups (or groups made vulnerable by research) around the world, who are employing grass-roots or ground-level strategies for improving the ethical conduct of research concerning them. Much of this is part of an overall push seen within communities towards community research governance. Therefore, while this relationship model itself may not entail 'empower' at this time, these sorts of efforts are often being done to work towards a goal synonymous with IAP2s' definition of 'empower' – wherein communities hold final decisional authority in the scope, conduct, and shape of research that is conducted with them, for them, or by them.

2.) Tygerberg Hospital affiliated biobanks - Public Facing Educational Video[4]

A need for improved research infrastructure in the African continent has led to considerable efforts to establish biobank networks in recent years the creation of international research consortia and initiatives like H3Africa. These efforts have by and large seen success and have contributed to innovative strategies for not only improving the network of biobanks in Africa but also encouraging the development of CE strategies. The faculty of medicine and social sciences at Tygerberg Hospital in South Africa received funding from H3Africa to develop a CE strategy with the goal of improving processes for involving participants in biobanking research at the hospital, and to contribute to the development of governance policies that could be used for H3Africa and other genomics research in Africa.[53] The researchers identified an educational video to address "evolving concepts in biobank science suitable for the understanding of the public" as their starting strategy.[53] The authors describing this event explain that the CE goal for the video was to "solicit community input into how best script, stage, and produce a video that relates to this subject matter and second, the video would serve as a springboard for broader community participation in the governance of genomic biobanking research".[53] The ultimate purpose of the CE project was to identify ELSI associated with genomic biobanking and to engage the larger community at Tygerberg Hospital.

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[4] Described in Staunton *et al.,* 2019.

The Researchers consulted a local CAB who were situated near Tygerberg Hospital. The CAB members were compensated per meeting to the equivalent of $5 USD. The authors indicate that an “education video” was considered a valuable approach to CE by the researchers and suggested a ‘co-creation’ of a video with the CAB.[53] Accordingly, the CAB and the researchers collaborated to develop content for the video, and the resulting conversations indicated that while there was anticipated overlap with what the researchers saw as valuable to communicate in the video, the CAB proposed content they would not have otherwise considered. The authors comment that in addition to this; “we tended to oversimplify some of the concepts, demonstrating the importance of including the CAB in the developmental stage.”[53] The video script was shared with healthcare providers and researchers once it was finalized via meetings with the CAB, and it was decided two CAB members would act in the video.[53] The day the video was to film, the authors explain that the CAB members dropped out, on the basis of expecting compensation beyond the $5 USD.[53] The authors describe that the CAB members were already informed of the amount of compensation they would receive and that they faced challenges balancing the autonomy of the CAB members to withdraw, and the continuation of the project. The lead investigator of the project noted that no guidelines exist for compensation for CE activities. They comment that paying CAB members a salary may blur the line between the CAB members’ role in representing the community, and ‘researcher’.[53] As a result of this conflict, the filming was postponed for two weeks, and eventually completed with two volunteer medical students. The authors note concerns that the biobank and the CABS relationship may have been tarnished because of this process; however, concerted efforts were made to continue a dialogue with the CAB and note that “the biobank and the CAB’s relationship continues to grow and develop” and recommend using CAB members for similar CE project regardless.[53]

This example points to a similar conclusion seen throughout this thesis; that CE is most successful when it is seen as an ongoing process rather than a single event. Arguably, the CE video could be considered both consult and inform, this CE is best categorized as inform. While the content was decided upon through collaboration with the CAB members and the research team, the authors indicate that the researchers decided a video was the best CE and then, according to the description, solicited the CAB for their insight. In addition, the video itself serves an informative role. It should be noted that this example of CE is one of many strategies taking place concurrently via what is known as the TRUCE model for CE associated with H3Africa, which employs a large network of CE strategies in biobanking.[17,53] Due to the TRUCE model, this example of CE was not the only ongoing effort for this community. This likely allowed for the positive continuation of the relationship between the researchers and the CAB, as it allowed for other opportunities to form a trusting relationship and to engage the community in other successful means.

3.4.1.3. Canada – Selected examples

1.) British Columbia – BC Biobank Public Deliberation Event[5]

The BC Biobank conducted a ‘deliberation’ public engagement event in 2007 to discuss the topic of biobanks with the BC public. The event was motivated by an observed lack of representation of the public interests and input from the public relating to biobanking and was initiated by the authors.[57] In addition, the BC biobank deliberation event was done to address

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[5] Described in O’Doherty and Burgess, 2009.

some of the criticisms that had been leveraged towards previous CE events conducted by biobanks, such as the UK biobank, where CE activities have been accused of not allowing for “genuine community input into policy”.[57] Accordingly, the authors sought to develop and conduct a public engagement event that incorporated CE at the level of governance for a possible biobank in the province of British Columbia in Canada.

The BC Biobank Deliberation was first designed in November 2006 by the authors (O’Doherty and Burgess) and with the guidance of worldwide experts on issues relating to biobanking and CE.[57] Following the initial planning portion, the event itself took place in April and May of 2007. The organizers sought to include a diversity of perspectives and developed a sampling method that recruited from the 5 health regions in British Columbia and made special provisions to ensure that the perspectives of Indigenous communities and communities of people with disabilities were included in the sample of participants. The sampling approach was done to ensure that an adequate variety of “life experiences, values, and discursive styles” were represented at the deliberative democracy event.[57,58] The event occurred over 2 weekends, and participants were provided with information on biobanks one week prior to the first event.[57] Day one of the first weekend of the event began with expert talks. These consisted of a diversity of speakers who were chosen to address the participants on a variety of topics. The invited speakers were also deliberatively selected to reflect a diversity of perspectives and expertise on the topic of biobanking, and its associated ethical issues. The invited speakers included experts in biobanking, Indigenous community leaders, and genomics experts.[57]

On the second day of the first weekend, participants separated into small groups to deliberate and discuss the concept of biobanks.[57] These discussions were guided by expert facilitators. On the first day of the second weekend, participants met again in small groups to consider and discuss specific recommendations for a BC biobank. During the second day of the second weekend, all participants came together for large group discussion to finalize the main points of the small group deliberations. Both deliberations were guided by expert facilitators who were there to encourage the conversation. Following the deliberation event, a report was developed by the authors, in addition to a number of publications discussing the event and its outcomes.[57,58] Key takeaways from the event demonstrated that participants, on the whole, considered a BC biobank valuable, but believed that such a biobank should have a "governing body independent of funders and researchers".[57] The authors note that these findings are consistent with the results of similar discursive events also done with the goals of improving CE in biobanking, improving trust in the research enterprise, and ensuring the relevance of research to community values and needs.[57]

This event seems to best entail 'involve' according to IAP2s' spectrum of public participation. It provides an opportunity to consider if there are degrees or gradations within each of IAP2's goals or tiers of involvement. While many other CE efforts have been done to understand the perspective of the community, which in turn may or may not, impact how a particular biobank is governed, the authors of the paper specifically note that this CE was done to incorporate the community at the governance level of a biobank. While the event itself is most fitting to tier 3, involve, it seems that the goal of the event better aligns with the motivations behind collaborate, which is to partner with the community and to allow their insight in developing solutions to problems. Providing a space for the community to influence the governance of a biobank may actually allow the community the opportunity to have decisional authority on aspects of the biobank. In this sense, this example of involving the community may lead to similar outcomes seen with ‘empower’, without necessarily employing a strategy that falls within a particular tier of public engagement.

2.) Quebec - CARTaGENE Public Consultation[6]

The CARTaGENE project in Quebec is a public resource genetic database that was developed to allow for an improved understanding genetic and environmental health factors in the province, and globally.[59] The repository consists of sociodemographic data and biological materials used for future research purposes.[59] CARTaGENE conducted two CE public consultation strategies from 2001 to 2003. These CE strategies were done with the goal of gaining an improved understanding of the public on the topic of biobanking, and the social perceptions of the provincial data repository initiative.[59] The public engagement strategies sought to consult members of the public representing diverse sociodemographic backgrounds from a number of Quebec cities.[59]

CARTaGENE began by conducting ‘qualitative’ focus group consultations with the public to identify issues on the topic of genomics.[59] The results from the focus groups were used to inform a qualitative survey, geared towards the wider Quebec public.[59] The focus group participants were selected to represent the variability of the Quebec public and were consisted of general questions the topic of genomic repositories.[59] The results of these focus groups found that participants were, on the whole, concerned with data security and facilitating public good and improved health.[59] In addition, the results of the focus groups showed that the participants

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[6] c Desribed in Godard, Marshall, and Laberge, 2007

were concerned with transparency in the ICF, and expressed the expectation that CARTaGENE clearly communicates to potential donors that biobanks collect data for future research projects that are not known or defined at the time of donating.[59] The focus groups were followed up with a 'quantitative' survey to ensure that the insight garnered from the focus groups "was representative of the whole".[59] The results of this survey indicated that the wider public is concerned about confidentiality, transparency, return of results and the commercialization of biobanks. The authors conclude their summary of the CARTaGENE CE by commenting that public consultation helps encourage the public to feel "empowered rather than exploited, being partners rather than simply subjects".[59]

This example of CE is best defined as 'consult'. It should be noted that this is an early example of biobank CE (the article discussing it is from 2005) and biobanking as a research practice was not as complex, nor as ubiquitous, as it is now. This earlier example of CE provides an opportunity to consider how CE in biobanking has evolved and progressed alongside biobanking as a research enterprise. The authors comment that the results of the focus groups and survey seem to show that even when considerable effort is made to improve transparency and accountability in biobanking, "…there is still a risk that the public will mistrust researchers and will simply not participate in sufficient numbers…"[59] This may be true, but it may also be the case that the CE strategies used to bolster trust and accountability in this example were not robust enough to achieve these goals. Indeed, this is also in concordance with IAP2s' spectrum, where 'consult' is lower on the spectrum, and therefore the ability for consultation to enhance complex, and oftentimes ineffable, concepts like trust and accountability may be limited. Moreover, the author's argument that the described public consultation was 'empowering' for participants is arguably not in line with today's understanding of 'empower'. Indeed, within the context of this thesis’ theoretical framework, this is explicitly true, as ‘empower’ is the last tier of the spectrum, and entails awarding community members final decisional authority on policies concerning them. The CARTaGENE CE, and the authors’ assessment of the event, provides an interesting case study to consider how the expectations and the opportunities posed by CE have evolved since biobanks started to become commonplace in public health research infrastructure.

3.5. Canada COVID-19 Biobank Internal Governance Policies Analysis

3.5.1. Document Retrieval

Canadian COVID-19 biobanks were identified using the online resource "Biobank Locator", maintained by the University of British Columbia. Through this resource, I identified a total of 10 biobanks specific to COVID-19 operating in Canada. Using the method described in section 2.4 of this thesis, I obtained 2 internal governance policies from Canadian COVID-19 biobanks. Multiple documents were available from online e biobank online, and one of the governance policy documents is the governance policy for a number of biobanks in British Columbia. One biobank provided me with a memorandum of understanding but requested that the document not be shared publicly and therefore was not included in this thesis.

Table 4: types of documents obtained from Canadian COVID-19 biobanks

Type of Document	**Available online**	**Obtained from biobank personnel**	**Declined/ or failed to share**
Management Framework	1	0	9
Protocol	0	1	9
Informed consent form	1	1	8

3.5.2. Document Analysis

BQC19

The BQC19 biobank is a decentralized biobank operating in the province of Quebec. The creation of the bank was mandated by the FRQS and the government of Quebec. The biobank consists of plasma and peripheral blood mononuclear cells, and samples are being contributed from several participating institutions in Quebec from the Health and Social Services Network, which is a network of hospitals across the province. The biobank donor population includes all adult patients who were tested for COVID-19 at a BQC-19 participating institution and consented to research, and incapacitated individuals who consented via a legally authorized representative.[70]

The BQC19 management framework notes that consent "will be modulated with respect to the usual standards that normally require a face-to-face meeting and obtaining a written consent using an Informed Consent Form (ICF). If participants were not able to consent in hospital, then research staff at the BQC19 were able to contact participants by telephone, or via verbal consent over the form. The framework explains that collected samples "will be retained as long as their scientific interest and applicable ethical rules warrant".[70] Participants can withdraw consent from participating in the biobank verbally or in writing "without explanation and without consequence on the quality of care and services" to which they are entitled. At the time a participant withdraws their consent, the samples will be destroyed; however, any analysis conducted up to that point with their samples will be retained to ensure the integrity of the research studies.

The BQC19 biobank has a governing committee that consists of a steering committee, a biobank manager, an access officer, a data manager, and a patient-partner committee. It also consists of a number of coordinators, including a data and sample coordinator, an ethics coordinator, and a participant engagement and knowledge transfer coordinator. It should be noted appears to be a paucity of details on some aspects of these committees as a whole; however additional information regarding the governance committee and steering committee can be found via their website. The governance policy which I first accessed in 2022 initially indicated that a public engagement committee would be established. Since first accessing that policy, the biobank has released an amended governance framework, which indicates that it now has a participant engagement and knowledge transfer coordinator. The role of this coordinator is explained to be to "...identify strategies to maximize participation…" and to "identify adequate tools to disseminate the discoveries based on data and samples…"[70] The participant engagement coordinator will also organize meetings, interview stakeholders (including site coordinators, nurses, and active BQC-19 participants), conduct data analysis, product drafts and reports of findings, and provide support to the sub-committee. Additional details could help determine if participants will play a role in contributing to the goals of maximizing participation and disseminating discoveries made during the course of the biobank. In assessing the currently available governance policy for the biobank, it is not clear the extent that participants are involved in such governance decisions. Accordingly, the extent of the BQC-19 biobank seems to entail 'consult' on IAP2's spectrum; however, this may change as more information is shared regarding the form and conduct of the biobank's public engagement approaches.[41] As such, this thesis may lend valuable insight to further developing the extent of the BQC-19's CE strategies.

BCCBN

The BC COVID-19 biobank network consists of a number of ‘partnering sites’ within the province of British Columbia, including the BC Children’s Hospital, the BC Women’s Hospital COVID-19 clinic, the UBC COVID Biobank, the Victoria General Hospital, Vancouver General Hospital, and St Paul’s Hospital. The BCCBN has also partnered with the Provincial COVID-19 Interdisciplinary Clinical Care Network (PC-ICCN), which has contributed to establishing a number of post-COVID-19-Recovery Clinics (PCRC) in the province.[71] The BC PCRC follows patients every 3-6 months, for 18 months, and continuing data is collected from participants. Its mission is to ‘quickly collect, store and distribute biospecimens and prepare for and enable a distribution capability to support COVID-related research studies.’[71]

The BCCBN governance policy’s purpose is explained to be to ensure the good governance of the biobank and ensure that the biobank is governed according to “the overarching principles of transparency, and accountability”. Its internal governance structure consists of an executive Steering Committee, a Governance Committee, a Scientific Review Committee, and a Patient Advisory Committee. The governance policy for this biobank explains that the Patient advisory committee “will be made up of patient partners who wish to contribute to the governance of the BCCBN”.[71] The purpose of the committee is to “provide opinion from a patent perspective” on the components of the biobank that have an impact on patient experience. No definition is given within the framework with respect to what aspects of biobank operations intersect with public experience.

The description of the patient advisory committee is not robust enough to infer much about the structure and make-up of the committee. However, the wording in the governance policy like ‘opinion’ seems to imply that the BCCBN’s approach to CE will entail ‘consult’.

Their approach may also entail something like the deliberative democracy event, described in O'Doherty and Burgess.[57] However, the extent of details in the governance policy is arguably not significant enough to draw a firm conclusion about the possible shape its CE will take, nor to infer what potential impact it may have on the governance of the bank.

Conclusion from document analysis:

It is an interesting observation that both the BCCBN and the BQC19 are the only locations where I was able to obtain governance policies (therefore the only confirmed Canadian COVID-19 banks who have put consideration into their CE committees), and both Canadian CE strategy examples identified in my literature review are from these same provinces. This may suggest that there is a correlation between previous infrastructure for CE and the general motivation or presence of CE at later dates. Indeed, there seems to be a paucity of recent examples of CE done by Canadian biobanks. This may have had an impact on CE in other provinces or biobanks, as a lack of CE may also entail a lack of a precedent for continuing CE strategies in Canada.

In assessing the available internal governance policies of Canadian COVID-19 biobanks, it is evident that there is not significant detail on the policies at this time, which may be a consequence of a lack of time or resources to establish these committees. Regardless, it should be noted that the most successful CE efforts seem to be the ones with clearly defined goals, and which begin before the biobank is established. This is because incorporating CE early on allows the community space to make governance decisions, in addition to providing insight on issues like informed consent, and reuse of secondary use of samples. Due to the fact that biobanks entail the use of samples for future undefined research, having clearly defined governance policies on these topics that are compatible with the expectation of the donor community, or general public, is important to help ensure the longevity and most efficient use of these samples for research.

Chapter 4: Scholarly Discussion of the Findings

4.1. Discussion

The primary goal of this project was to identify the current and future role of CE for Canadian COVID-19 biobanks and evaluate them according to the recommended best practices for CE in the literature and normative guidance documents. In this section, I consider the results of this thesis within the conversation on CE during the COVID-19 pandemic. I discuss and assess my results within the context and recommendations of the normative guidance and the conversation in the literature on CE and biobanking. I conclude by discussing the limitations of this study.

This thesis continues the discussion within the biobank literature on biobanking and CE. CE has become an increasingly common approach in public health research, as it is done to establish a discursive space between community members and researchers to improve the design, purpose, and outcomes of projects for all parties. As CE strategies become more commonly employed (and increasingly required by funders), it is valuable to ensure that research makes use of CE strategies in ways that encourage its associated benefits.[17] Such benefits can include enhancing the public voice, increasing trust and improving relationships between researchers and the public, augmenting consent processes, and improving the capacity of communities overall.[17] This is important because ineffectual or poorly planned CE efforts can instead become burdensome for both community groups and researchers. CE should be implemented and developed with sufficient forethought.[72] Arguably, this claim remains true despite the extraneous pressures brought on by the pandemic impacting COVID-19 biobanks.

4.1.1. Community Engagement in public health research during the COVID-19 Pandemic

Biobank scholars have previously commented on an observed paucity of CE and public consultation in the context of genomics research. Puerta and colleagues note that the results of a 2019 study found that in the context of genomic research, “only one third of studies involved the public”.[13] As this data stem from 2019, no identifiable studies at the time of writing consider the decline of CE seen specifically with biobanks during the COVID-19 pandemic; however, scholars have commented on the observed decline, or lack, of community, public, or patient engagement efforts in public health research overall during the pandemic. Denegri and Starling comment that the pandemic highlighted the fragile state of patient engagement in research, noting that even in regions where CE infrastructures are the most developed, researchers "...defaulted all too easily to excluding patient voice in research by dropping patient engagement".[73] They highlight a UK Health Research Authority study, which found that in March 2020 the number of research studies involving patients fell from 80% to 22 %.[73] This decline was justified by a need to rapidly establish studies which impacted the decision, or perceived need, to incorporate patient engagement in the research and policy design.[73] The authors note that the perception that patient engagement would slow down research projects during that pandemic was based on "...incorrect assumptions of patient groups’ actual capacities and readiness for involvement".[73]

Similarly, Gilmore and colleagues argued that CE in the context of COVID-19 research could provide a valuable opportunity to create solutions developed by and for communities to target the challenges posed by the pandemic.[72] Indeed, community-level interventions were potent avenues to reduce the negative impact of the COVID-19 pandemic. With respect to biobanks, community members volunteered invaluable biological samples to research repositories. Concurrently, communities were expected to minimize the spread of COVID-19 during vaccine development and avoid going into the public as much as possible. Despite this, Gilmore and colleagues highlight a "…lack of involvement of communities within COVID-19 policy making".[72] Similarly, Rajan and colleagues note that few WHO Member States incorporated engagement with "civil society and community groups in primary discussions" in health policy development and in identifying research priorities in the early days of the pandemic.[74] Early-stage priorities of global governments and the research community were to gain an improved understanding of the virus and to develop epidemiological interventions, rather than develop CE strategies.[72] We may question why CE and its associated benefits must be sacrificed or de-prioritized, in the pursuit of research; indeed, this thesis maintains it should not.

Interpreting the above discussion from the lens of IAP2s' spectrum for public engagement would not allow much space to comment on this overall lack of CE in public health research during the pandemic. However, if we expand our theoretic lens to include Facilitating Power's adaptation of IAP2s' framework, we can contextualize how 'ignoring' the public during COVID could have had negative impacts on the public.[41,42] Facilitating Power comments that ignoring the community in the decision-making process sends the message that the "voice, needs, and interests" of the community "do not matter."[42] While this approach to CE may save policymakers and researchers time in the immediate moment, the outcomes of policy and research that ignores the community is a set of decisions that have not been "vetted" by the community, which may lead to issues downstream, including potential fallout between parties (in this case, biobanks and/or donors and the public).[42] The increase in CE efforts seen within health research is directly tied to the overall goals of improving health inequities and equally distributing the benefits and burdens associated with public health research.[75] As such, engaging communities impacted by research should not be seen as simply a recommendation or an option for public health researchers, but an obligation. This claim may hold greater legitimacy in the context of the COVID-19 pandemic, wherein marginalized communities bore a disproportionate degree of the negative impacts [63,64] [[7]] These are predicates upon which this discussion, and indeed this thesis, rest: CE for public health is valuable in-and-of-itself, but it is integral for biobanks. This is because biobanks can produce results that have vast influence on vaccines, policies, and the overall way of life of entire publics, and because it helps to bolster trust in the biobanking enterprise.

4.1.2. Trust and Transparency

One theme seen with this thesis is that biobanks conduct CE efforts to improve the transparency of their research efforts. Transparency itself is an important goal, yet arguably, it is not the main goal of biobank CE. Rather, transparency facilitates accountability, which helps to ensure the sustainability and longevity of a biobank, while also improving the relevance of research for the communities impacted by said biobank's research.[7] Indeed, a lack of transparency can, and has, negatively impacted the longevity of research in the field of genetics and genomics, and genetic data has been misused by researchers in the past. Notable genetics research scandals, like the Havasupai tribe blood scandal in the United States or the Nuu-Cha-Nulth blood scandal in Canada, lend credence to the concerns of the public that their biological samples may be misused by researchers.[76–78] In consideration of this, CE serves an integral

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[7] Recall that the shift to participatory research methodologies, which led to the increase in community engagement, was largely spearheaded by marginalized community groups in order to combat unethical research practices.

bioethical role in biobank research, and as Lemke and colleagues note, it may be "instrumental in preventing barriers to future research".[39]

It is arguable that if a biobank is not conducting CE, it is not fully transparent. Gibson, Alxer and Lemmens note that transparency can be facilitated by improving the availability of information on biobank access and procedures, improving the relevance of the results of research, and clarifying who is being given access to data.[10] Accordingly, increasing the availability of governance policies or research results is a way that biobanks can improve transparency in their operations and create an avenue to engage a community of donors. The results of this thesis revealed that few COVID-19 biobanks in Canada followed this recommendation; 1 of 10 total governance policies was easily found online, and I accessed 1 policy by emailing the coordinator of the biobank directly. Beyond giving access to such policies, it is also important to consider the accessibility of information available to the public. The biobanking enterprise is growing increasingly more complex year after year.[5] Accordingly, so to increases the degree of literacy required to understand public-facing information about a given biobank. Accessible summaries or information sheets directed towards the public may be more valuable than a biobank's original governance policies to improve transparency. Point of fact, developing a public-facing fact sheet is CE; it falls into IAP2's category of 'informing' the public of a biobank's governance policy.[41] It follows that the extent of a biobank's transparency with the public may also increase or decrease according to the kind of CE strategies employed by a biobank. The literature on the topic of genomics and CE emphatically argue that transparency is tied to public trust, and so the same can be said for the degree of trust the public can have in a biobank.

It should be noted that it is likely that I was not able to identify all Canadian COVID-19 biobanks through my scope, nor all examples of CE in biobanking. In addition, the observation that there is a general lack of transparency in the governance policies of Canadian COVID-19 biobanks does not mean that this was done intentionally or with malintent, nor does it mean these biobanks are not ‘trustworthy’. Rather, this could be seen as a challenge stemming from the way that biobanks are often embedded within institutions. Biobanked data is often stored in a hospital or a university, and these samples may be contributed to larger biobanks used for a wide variety of research purposes. Additionally, hospitals or universities that contributed COVID-19 biosamples to larger, international, biobanks, may themselves have ongoing CE strategies through patient partnership or CE committees. Conceivably, CE may have occurred via patient partnerships and would not have been captured by my scope. In addition, not every biobank or CE effort will culminate in a publication. This lack could also be a result of a paucity of resources, both time and funding, to allow for meaningful CE. Importantly, ‘time’ as a resource also includes time invested. As seen elsewhere, many CE events were successful because of continued and well-established relationships between community groups and researchers.[54,55,68] The Tygerberg Hospital biobank example highlighted in the results of this thesis provides an example of how insufficient investiture on the part of researchers to establish a relationship with the community can result in difficult or failed CE attempts.[53] This is evidenced within this example, as once the relationship was better established, their CE approaches were described as more fruitful going forward. As such, it is clear that CE requires sufficient consideration into the context of a community to facilitate trust and ensure CE efforts are well-done.

4.1.3. Community Engagement and the 'world wide' web

Despite physical barriers and time challenges seen with the pandemic, the social and scientific value added to research projects via CE give sufficient reason to researchers and governments to retain the practice during the pandemic. Even if this were not the case, developing CE efforts has arguably never been simpler than in the era of COVID-19. The pandemic saw the world shift *en masse* to online platforms of communication to encourage social distancing measures, as well as disease confinement and containment.[79] The shift to online platforms means that, in many ways, CE efforts are more available than ever for biobanks and the public. This seems to be supported by commentary from Brothers, Cadigan, and Moodly, who note that their upcoming survey results, conducted with ISBER and biobanks operating during COVID-19, show some biobanks turning to online CE methods.[21] However, when considering online CE efforts, it is important to keep in mind that the shift toward community-based research methodologies has occurred in tandem with calls for improved accountability and ethicality in research with minority communities in Canada and around the world.[80]

The surge in CE strategies can be largely credited to the work and resistance of Indigenous community groups demanding more ethical research after generations of colonial and exploitative research practices in the field of genomics.[80,81]Unethical research practices in the field of genomics, among other fields of research, created an understandable culture of distrust towards research and a hesitancy to contribute data to genomics research among Indigenous communities worldwide.[81] [8,9] Despite socially and culturally valid hesitations seen within Indigenous communities to donate data for genomics research, the observed lack of Indigenous genomic data for research purposes has been associated with large health inequities among such community groups.[81] It can be inferred that COVID may similarly pose health inequities towards such groups, and the negative impacts of these inequities may be exacerbated by the culture of distrust towards genomics in Indigenous communities. In consideration of this, I argue that online methods for CE should be carefully considered by researchers.

Online methods for CE should be given due consideration, because, as Sanders and Scanlon note: “the role of technology and importance of access to high-speed broadband has become glaringly obvious during the COVID-19 pandemic”.[82] Indigenous communities in Canada, but particularly Inuit and northern First Nations communities, are disproportionally affected by the ‘digital divide’.[34] Shifting to using methods for CE may exclude the exact

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[8] The Nuu-Chah-Nulth blood scandal, which took place from 1982 to 2003, began as a research project on the prevalence of rheumatoid arthritis within the Nuu-Chah-Nulth First Nations. The study, conducted by Dr. Richard Ward at the University of British Columbia, sought to identify a genetic predisposition for rheumatoid arthritis in the Nuu-Chah-Nulth population and identify a cure. Study participants signed a consent document for expressly this purpose; however, when Ward failed to identify any biomarkers for the disease the study was shelved. Ward eventually left the UBC and brought the samples with him to Oxford where they became the source of information for over 200 papers on multiple disparate research projects. Ward even indicated he planned to use blood for research into the evolutionary history of First Nations DNA. Ward’s research had veered far from the original purpose of the collected samples, and the consent given by the Nuu-chah-nulth participants. In response to these unethical research practices, the Nuu-chah-nulth community established a community research ethics committee to review future proposals involving the Nuu-chah-nulth and retrieve the blood samples from Oxford University.[77]

[9] The Havasupai Tribe Scandal began in 1989, wherein the Havasupai tribe where asked to blood donate samples for genetic research to determine why the incidence of diabetes was increasing in the Havasupai community. The study was undertaken by a researcher who had a pre-existing and trusting relationship with the Havasupai tribe, and an additional researcher who misused the donated Havasupai samples to conducted research on the prevalence of mental illness in the community, violating the informed consent of research participants. All participants were under the impression their blood would be used to study the genetic link to diabetes, only. After determining that there was no genetic link to diabetes in the community, researchers at ASU continued to conduct research on mental disorders, “inbreeding, alcoholism, and the origin and migration of the tribe from Asia without participants’ further consent. Migration research not only violated consent, but also developed theories that conflicted with core cultural beliefs of the tribe. The tribe sued ASU, and settled in April 2010 for a payment of $700 000, the return of the samples, community scholarships, and federal funding for a health clinic for the tribe.[78]

communities which Canadian researchers are obligated to engage, in accordance with Chapter 9 of the TCPS-2.[11] As such, biobankers should be cautious in developing their CE policies, ensuring that they have accounted for the social aspects and lived realities of the populations they seek to involve. If online engagement allows for biobankers to reach a greater portion of the community or is necessary for CE to occur, they may consider employing hybrid methods. This could, for example, involve coordinating with community leaders to have a communal meeting area with reliable internet to allow community members to congregate during CE events. The results of this thesis' narrative review indicate that CE can take on many different shapes, and different approaches may better suit different biobanks. Different communities may expect in-person community events as well, and some may not consider online CE acceptable.

The above implies one of the fundamental expectations of participatory research, which often is that communities expect that researchers have put in significant effort to develop a relationship with them before conducting any research. This seems to also contribute to the success of biobanks, as seen with Dang and Chen, who describe how a longstanding relationship with the Asian American community in California allowed for more successful Cancer biobanks for research to improve the outcomes of Asian Americans with Cancer.[68] If biobank researchers and a given community indeed do have a well-established pre-existing relationship, the researchers should be aware of community-level specifics, such as access to the internet and the expected social customs of said community. In many ways, this also reflects the recommendations of the normative documents, many of which note that CE is an ongoing process. Indeed, CE for biobanks may have to begin well before a biobank is established, which could entail ensuring a positive community-researcher relationships before conducting research as well as after. This fundamentally involves a gestalt shift in many if not most biobank research practices, where biobankers and public health researchers can come to understand that the results of a research project can, and often do, have long-lasting impacts on communities both positively and negatively. Often, the project does not end when the file is closed for those people whom the research is on or about. This is particularly important to keep in mind for biobanks, which may continue to produce results which directly impact communities for years if not decades.

4.2. Limitations

While this thesis maintains that CE is as valuable as all other governance considerations for biobanks the results of this thesis indicate this point may not be upheld within the wider biobanking community. It is likely that researchers' overall priorities when establishing a biobank, especially biobanks which will target diseases of a pandemic nature, is to ensure the biobank is able to collect a sufficient number of samples, that staff are safe from biohazards, that data are well managed, and that participants have consented to the use of their data. This is understandable, these are indispensable components for biobanks; poor management of these aspects could pose serious risks to institutions, researchers, and research participants. However, it is also possible that several study limitations impacted my ability to identify Canadian COVID-19 biobanks and their associated CE approaches.

Indeed, a main limitation of this study is seen with the methods for identifying Canadian COVID-19 biobanks, and the challenges faced with accessing the internal governance policies of such biobanks. While the 'biobank resource centre' was a helpful resource in identifying Canadian COVID-19 biobanks, it very likely does not capture all COVID-19 biobanks operating in Canada. This is because institutions such as hospitals often establish biobanks internally, or may be investigator-initiated, and as a result likely do not publicly advertise when biobanks are established. These are often smaller repositories with fewer resources available for additional personnel, and the energy required to publicly broadcast the governance of biobanks. Biobanks established by hospitals or universities therefore would not been identified by my search if they do not have an online presence or were not advertised to the public.

Additionally, COVID-19 biobank researchers in Canada may have conducted research under the auspices of an international pharmaceutical company or sponsor. As such, biobanks that consist of the Canadian public's COVID-19 biosamples likely exist outside of the Canadian research enterprise. This creates further challenges in defining community for international sponsor-initiated COVID-19 biobanks. There may be biobanks that were developed to target COVID-19 in Canada but were not captured by my search. To build on and improve upon this limitation, future studies could directly solicit hospitals and research universities within Canada for information on COVID-19 biobanks and ask to access their associated internal governance policies. Regardless, it should be noted that these limitations also provide interesting results for this thesis, as they demonstrate that the recommendation that biobanks are transparent and accountable is often not fully achieved by biobanks. Another possible limitation of this study is that CE efforts may be ongoing through patient partnership efforts at hospitals or other institutions. As a result, CE may not be explicitly linked to the biobanks I identified, although they could be implicitly linked as a result of CE with patient partner groups. In addition, it is reasonable to expect that not all COVID-19 biobanks, nor CE efforts for such biobanks, would result in a publication. I would have therefore not identified these examples in my search.

An additional limitation of this project is that my search returned few internal governance approaches and limited the degree of primary sources available for document analysis. While I was able to find 11 COVID-19-specific biobanks in my search, the response rate of these biobanks was low, as was online accessibility for documents of interest (i.e., internal governance policies). This resulted in a low number of primary sources and evidence for analysis of this thesis. To manage the impact, I introduced a CE comparator group. In addition, widening the scope of my comparator group to look at the literature on CE before and after the pandemic would have also provided valuable data to this thesis. However, these methods are beyond the scope of this thesis, given its limited timeline. In spite of these limitations, at the time of writing, this is the first study inquiring into Canadian COVID-19 biobank's CE policies. As such, these limitations could be addressed by future studies inquiring into a similar topic.

Chapter 5: Conclusions and Future Directions

This thesis sought to address the question of how biobanks have employed CE in their governance structures in the past and to consider the future role of CE in Canadian COVID-19 biobanks. The first objective of this study was to investigate and document the scope of biobank CE strategies which were in operation prior to the pandemic. To contribute to this goal, I conducted a narrative literature review on the topic. This review revealed that biobanks have previously employed a number of variable and similar approaches to conduct CE. In addition, it demonstrated that biobanks often employ multiple CE strategies at the same time. I assessed these strategies from the theoretical lens of the IAP2s spectrum for public participation to lend insight into the different strategies for CE previously employed by biobanks.

The second objective of this thesis was to investigate the governing policies employed by COVID-19 biobanks in Canada and identify the core qualities of their CE policies. This assessment was done following a literature review, normative document review, and narrative review which were all conducted to adequately better situate my content analysis in the context of CE and biobanks. In this review, I found that there is a lack of details on the CE strategies of available governance policies. Such a lack of details made it difficult to identify particular qualities of the biobanks CE policies. However, this lack of detail can be seen as a positive, as it could allow for the results of this thesis to offer additional value by providing examples and details on previous CE strategies. In conducting this document analysis, I found that on average, there was a lack of availability of governance policies of Canadian COVID-19 biobanks. Therefore, simply providing this information in an accessible format is a valuable first step for biobanks seeking to improve transparency and accountability towards the public in their governance approaches.

The results of this study have implications for Canadian COVID-19 biobanks, but potentially also for other COVID-19 biobanks operating internationally. In addition, the results may be relevant for future pandemics or diseases that have a global impact. My results indicate that CE activities may hold a fragile position in influencing policy or governance decisions when time pressures become an external factor for biobanks. Future studies on this topic may also consider conducting surveys or qualitative interviews with biobank personnel to allow for an improved understanding on the role of CE in their governance policies not captured by governance policies. This also could help to better understand how Canadian biobanks are involving CE in their governance structures as a whole.

Future studies or research initiatives could also involve building out the information that was found in the ‘biobank locator tool’. This was a very useful tool to identify biobanks. Given the sheer volume of biobanks in Canada, simply identifying biobanks may be a limiting step for laypeople interested in gaining improved knowledge on biobanks. The existing biobank locator tool used in this thesis could be either updated, or similar tools could be created by different health regions to document biobanks. This would certainly contribute to improving biobank transparency at an ontological level, as it would make the public more aware of biobanking activities ongoing in their communities. Additionally, this tool could have governance policies automatically uploaded for all biobanks documented in then of network to streamline the process of accessing biobank governance frameworks and policies

Another possible future application of this thesis could be in expanding the definition of CE within the TCPS-2 in Canada. As discussed, the TCPS-2 focuses on encouraging CE in the context of research with Indigenous communities. As a result, researchers, REBs, and funding agencies may not have an expectation for CE to take place outside of the context of research with

Indigenous communities. Moreover, there is no prescriptive or regulatory influence to ensure that CE occurs with other communities who may benefit from it. Expanding the application of the TCPS-2 chapter 9 is one possible approach to widen the scope of CE in Canada and ensure that its associated benefits are incorporated into the wider health research enterprise.

As the number of biobanks continues to increase, it is more and more valuable to consider the role of the public in defining the priorities of such research repositories. The COVID-19 pandemic demonstrated that research done on the public and the lived realities of the public are far more intertwined than may have previously been understood. As such, forming a channel of communication that contributes to the goals of improving trust, transparency, and accountability are invaluable for biobanks to encourage their relevance and sustainability. Beyond this, public health research (and research repositories in their capacity to facilitate public health research) exist expressly to serve the public and improve public health. CE allows for the opportunity to develop innovative strategies that can, and have, directly led to improved public health, and more successful biobanks. In consideration of this, this thesis maintains that CE is integral in improving the ethical use, conduct, and governance of biobanks in Canada and worldwide, both within and outside of the context of a worldwide public health emergency.

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