CANADIAN ASSOCIATION OF RESEARCH ETHICS BOARDS
L'ASSOCIATION CANADIENNE DES COMITES D'ETHIQUE DE LA RECHERCHE

VIRTUAL REB (vREB) DEBRIEF

Preface: The Virtual REB is a CAREB-ACCER professional development initiative that facilitates discussion on a series of research ethics case studies. While the cases presented are study overviews rather than full protocols, they are designed to include enough information for a fulsome discussion of the ethical issues entailed.

Case Studies are posted for CAREB-ACCER members across Canada to contribute their thoughts on relevant ethical issues as if conducting a research ethics review. The case debrief that follows is a collaborative product of VREB review. Where applicable, comments are supported by relevant legal and regulatory references, in particular the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2).

This debrief is archived in the professional development section of the CAREB-ACCER website as a resource which can be used by CAREB-ACCER members to support the orientation and training of REB members and professionals within their own institutions. The VREB Advisory Working group acknowledges that research ethics opinions are often seen through the lens of context and are open to interpretation. As such, opinions may vary; however, these variations may be the seeds of professional discussion, learning, and development which are the goals of this exercise.

Case Study #1: Influenza Transmission in Hutterite Communities

Introduction

It was noted by some reviewers that if this study came to an REB that was not familiar with this particular population, the REB would do well to consult an ad hoc advisor with the specific knowledge and expertise required (TCPS2 Article 6.5). Also, Article 9.8 of the TCPS2 states that researchers—and arguably, this can extend to REBs also if they are to conduct appropriate research ethics reviews—have "an obligation to become informed about, and to respect, the relevant customs and codes of research practice that apply in the particular community or communities affected by their research" and that "inconsistencies between community custom and [TCPS2 policy] should be identified and addressed in advance of initiating the research, or

as they arise." These comments are a reminder to REB reviewers not to succumb to personal bias, assumptions or stereotypes when reviewing research. Some of the reviewers who contributed to this debrief appeared to have knowledge of Hutterite colonies and others took it upon themselves to do some research for this exercise.

1. Ethical Issues related to PARTICIPANTS

Population Characteristics

Given the unique and isolated nature of Hutterite colonies, reviewers questioned whether this is the best population to be studied. It appears that there is a lack of community engagement in the conduct of the research (TCPS 2 Article 9.2). It may or may not be appropriate that only community elders are involved in the research planning discussions; however, the researcher should consider extending discussions to the entire community. Further, the generalizability of the results to the general population is doubtful (TCPS 2 Article 2.7).

Vulnerable population

Reviewers identified issues of vulnerability, given that the Hutterite community and children are the focus of the study (TCPS 2 Article 4.7). Specifically, concerns were raised whether it is fair for the children to bear the burden of a study that is meant ultimately to benefit adults (TCPS 2 Articles 4.4, 4.6; Chapter 9, Section C). Unanticipated issues may arise given the uniqueness of the Hutterite culture (TCPS 2 Article 6.15).

Inclusion Criteria/Exclusion Criteria

No inclusion criteria are provided in the case study notes. In a full protocol, it would be expected that the researcher would explain how it would be determined if the adult and children participants were healthy enough to participate in the study (TCPS2 Article 4.1).

2. Ethical Issues related to RECRUITMENT and COMMUNITY ENGAGEMENT

Pre-existing relationships and power differentials characterize the proposed recruitment strategy. Reviewers remarked on the clear power differential between adults and children, heightened when an adult—such as a teacher, community leader or elder in a hierarchical community—is in a position of authority or responsibility. Further, this power differential is likely to be particularly strong in a cloistered community with limited outside exposure (TCPS2 Article 3.1).

There is also a power differential between the community leaders and the teachers. Community leaders have influence over teachers' employment within the community. Hence, teachers may feel a sense of obligation to fulfill the wishes of community leaders through successful recruitment. That is, teachers may feel they must agree to engage as recruiters and they may feel a need to secure positive responses from students, which could lead to the exertion of (conscious or unconscious) pressure on students to agree to participate (TCPS2 Articles 3.1, 9.5).

Differences in recruitment processes across communities could undermine the research design by introducing inconsistencies; therefore, the specifics of the intended recruitment process for each community needs to be determined in advance. A recruitment strategy must be identified for the adult community members.

As an outsider to the community, it is appropriate that Dr. Green engages support from a community member during the recruitment process. Chapter 9 of the TCPS2 may be considered here. As mentioned, some reviewers had experience with and knowledge of Hutterite communities and contended that permission is normally required to visit this type of closed society. If Dr. Green relies upon community members to recruit participants, it will be important to specify how those community members will be briefed about the rights of research participants, the expectations regarding confidentiality, the risks and benefits of the research, the importance of free and informed consent, and the utilization of the approved research protocol. Given the tight community setting, it will be particularly important to specify who will be informed about individuals' rights and decisions regarding participation. Ideally, in order to maintain confidentiality, it should be stipulated that recruitment assistants instruct potential participants to contact researchers directly if they wish to participate in the study.

The expectations regarding recruitment could be captured as part of a broader research agreement specifying the terms and undertakings of the research team and community members. Such agreements are expected when researchers negotiate research projects with Indigenous communities (TCPS2 Article 9.11) and could be appropriate in a case like this where the researcher intends to work with community leaders as gatekeepers for a distinct cultural group. Engagement during the design process with groups whose welfare may be affected by the research can help to clarify the potential impact of the research and indicate where any negative impact on welfare can be minimized (TCPS2 Chapter 1). Community events to support broad engagement could be introduced where the proposed research study is presented to the entire community. Questions about social acceptance, patriarchal hierarchy, and the customs and practices of the colony could then be acknowledged and addressed prior to the study (TCPS 2 Article 9.8).

Broad community engagement is essential for the proposed research because population immunity—commonly known as the herd effect—means that immunity levels for all community members (not just the children and adult community members who agree to participate in the research) can be affected by the provision of vaccinations or placebos to the children of the community.

An additional consideration is the availability of the vaccine outside the research study. Community members might perceive that participation in the study is the only means to have their children vaccinated. Some reviewers familiar with this population commented that Hutterites have been known to refuse or delay immunization, so the research study might be presumed to provide access to an otherwise unavailable vaccine (TCPS 2 Article 11.6). However, agreement by community leaders for the community to participate in the study would seem to indicate that vaccinations are not verboten.

3. Ethical issues related to INFORMED CONSENT

The consent process is described as Dr. Green seeking consent from each community leader on behalf of the members of his community, thus presenting an influence of a power relationship (TCPS 2 Article 3.1). Due to the nature of this patriarchal society and the description of the informed consent, adult participants are given no opportunity to voluntarily consent (TCPS 2 Article 3.2). Children seem to have no role in assenting and there is no provision for consent by their legal guardians (TCPS 2 Articles 3.9, 3.10). Elements for ongoing consent during the vaccination and subsequent monitoring period or withdrawal by participants at any time during the research have not been described for either age group (TCPS 2 Articles 3.3).

The current consent process does not appear to respect the autonomy of participants and thus violates the provisions for voluntary consent as set out in TCPS2 Chapter 3. Alternate means of consenting are contemplated in TCPS 2 Article 3.7 but the current study does not meet the required criteria. Consequently, it would be concluded that the process of consent proposed by Dr. Green is not compliant with the provisions of TCPS 2 and accordingly, the REB may request revision.

4. Ethical Issues related to RISKS AND BENEFITS

Reviewers felt that this study, which involves a drug intervention, presents the potential for both physical and psychological risk (TCPS2 Article 11.4, 11.5, 11.6). As with any drug intervention, it is essential to list all of the potential risks and possible adverse reactions to the vaccinations for the participants, so that they are well informed (TCPS2 Articles 1.4). Plans to address serious adverse events need to be outlined and included in the protocol (TCPS2 Article 11.7). The researcher is required to provide a detailed procedure for the setup and operation of the vaccination clinics including the standard of care for vaccination in the region.

It is the responsibility of the researcher to justify the use of a placebo for this study. The use of placebo may not be deemed ethical by the REB as children who receive the placebo will be left at risk of contracting influenza (TCPS2 Article 11.2).

The children or adults may feel compelled to participate by peer pressure within the colony which may translate into psychological stress. They may also suffer from emotional distress related to receiving an injection. These risks should be identified along with a mitigation strategy to address them. An opt-out option for participants with the protection of their identity might be part of the strategy.

Another potential risk related to this study is the economic impact to a colony where the participants receive the placebo versus the influenza vaccine, and the community suffers an influenza outbreak. There may be an economic loss for the community if the adults contract influenza and are sick for a period of time.

5. Ethical issues related to CONFIDENTIALITY AND ANONYMITY

The researcher indicates that data will be anonymized and the research files safeguarded in keeping with the research institution's privacy and confidentiality policy. Detailed information is required regarding the data management plan as legitimate concerns are raised regarding how effective provisions for privacy may be given considering the unique nature of the population under study.

As it is proposed that teachers will recruit the child participants, it is unclear how the identity of those who choose to participate, and those who choose not to participate, will be protected (TCPS2, Articles 5.2, 9.16). Details must be provided for how the data will be held in confidence and reported anonymously to protect the privacy of the participants and communities. An explanation for how research results will be reported back to the Hutterite communities is required. The Hutterite community leaders will likely share rights over the research data and if they choose to be identified in publication there may be a risk of identification/stigmatization. Each colony may want to engage in the interpretation of the data and the options for dissemination of results (TCPS2, Article 9.17, 9.18). These details should be fully discussed and understood so that an informed agreement is made that takes into consideration the best interests of both the researcher and the community participants.

Measures for safeguarding the information "in keeping with the research institution's privacy and confidentiality policy" should detail: who has access to the data; data collection methods; use of the data; plans for dissemination; retention duration, location and storage security; and disposal methods (TCPS2, Article 5.3). Provincial legislation for the protection of personal health information access and privacy must also be respected (FOIPPA; eHealth Act, BC; PHIPA, ON).

Participants should be informed that infectious disease outbreaks such as influenza must be reported to public health agencies in Canada; should there be an outbreak of influenza in one of the Hutterite colonies during the research, identifiable data will need to be disclosed to the appropriate health authorities (TCPS2 Articles 5.1, 5.2).

If this research is a clinical trial, it should be registered at ClinicalTrials.gov (TCPS2, Article 11.3) and data retention will need to meet Health Canada standards for 25 years

The submission does not include any plans for secondary use of data. However, as per TCPS Chapter 5, any plans for secondary use of the data should be made known to and discussed with the participant community and details included in the informed consent form and submitted to the REB for review. The wishes of the Hutterite communities should also be strongly considered and respected when the secondary use of data is being contemplated.

Acknowledgements

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References

Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, & Social Sciences and Humanities Research Council of Canada. (2014). *Tri-council policy statement: Ethical conduct for research involving humans*. Ottawa, ON: Her Majesty the Queen in Right of Canada. Retrieved from http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/