CAREB-ACCER vREB Case Study Debrief - Case 3: Hypertension in a First Nations Community (Case study courtesy of the Secretariat on Responsible Conduct of Research)

The Virtual REB (vREB) 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. Results will be compiled and presented in a case debrief that will be archived on the CAREB-ACCER website as a training resource which can be used by CAREB-ACCER members to support the orientation and training of REB members and professionals within their own institutions.

We acknowledge 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. If you have comments on the case or debrief, we encourage you to start or join a discussion on the vREB section of the CAREB-ACCER online forum

CAREB-ACCER received a total of 8 responses to the case study survey with only 3 being complete responses.

While CAREB-ACCER survey respondents identified that they believed that this case study is Above Minimal Risk (AMR) and thus, should undergo full board review (per TCPS2 article 2.9) vREB Advisory members acknowledged that different REBs may have a different interpretation on the level of risk of the case-study. Some vREB members felt the research could be deemed as minimal risk and undergo delegated review, while others felt that although it was potentially minimal risk a full board review would allow for special considerations and others felt it was AMR so would undergo full board review. Determining level of risk would depend on a number of factors within the REB and forthcoming details related to the research. Factors that might determine how the REB interprets the level of risk included: the level of Indigenous expertise by reviewers conducting the review or on the REB; the use of blood sticks; the potential identifiability of the community; and additional information regarding future genetic research and/or bio banking may place it AMR.

Based on the facts presented within case study #3, the vREB identified the following ethical issues related to the following categories below:

Community Engagement, Cultural Knowledge, and Research Agreements:

- Note: Manitoulin Island is comprised of multiple (seven) distinct indigenous communities. Are the researchers aware of the different communities and that each community may require different and/or specific research requirements?
- Community engagement should have started before the ethics application was submitted to ensure that each indigenous community is engaged and supportive of the research (TCPS2 Articles 9.1, 9.2, 9.3, 9.4.).
- The medical resident conducting the research may be a novice researcher; and should consider having a respected member from each indigenous community join the research team to support engagement, collaboration, and trust (TCPS2 Article 9.12)
- How will the researcher ensure appropriate cultural knowledge is utilised throughout the study? (TCPS2 Articles 9.8, 9.15)
- The case study identifies that the researcher will meet with Elders to “explain the project”. However, Elders may not be the people that the project should be explained to; it may be the leaders of the community. The researcher needs to identify who the appropriate community members are that should be involved and who consent is required from (i.e. Chief and Council, or Carriers of Wisdom).
- The researcher should explain how permission to conduct the research will be secured from each specific community (TCPS2 Articles 9.1, 9.6).
- TCPS2 Article 9.8 identifies the need for respect for community customs and codes of research practice; how the researcher will communicate must be identified in advance of any research and relate to the specific research community.
- A research agreement is required (TCPS2 Article 9.11) and should address reciprocity in relation to the community context (TCPS2 Chapter 9 preamble).
- How will the principles of OCAP™--Ownership Control Access and Possession be honoured? OCAP™ protects all indigenous cultural, genetic/biological materials for future use (TCPS2 Articles 9.8, 9.16).
- Per TCPS2 Article 9.3, research ethics review is required by the institutional REB and any responsible community body recognized by the First Nations authority. To conduct research on Manitoulin Island, the researcher must provide an ethics certificate from Manitoulin Anishinaabek Research Review Committee (see http://www.noojmomade to establish research capacity in the community (TCPS2 articles 9.14).

Research Question and Method:

- The research questions don't seem to truly relate to the issue identified in the background of the case. Literature has already revealed evidence that cardiovascular disease is increasing and that traditional methods to deal with this issue are not necessarily the most effective in indigenous communities, yet the research doesn't seem to really touch on how to effectively address the issue of cardiovascular disease within these communities. It only proposes to evaluate the incidence of hypertension.
- The research question may have scientific issues: Etiology of hypertension is clearly understood as primarily two factors - genetics and environment. Examining hypertension in this population may result in a form of discrimination if the social determinants of health are not also adequately considered. The cascading physical/genetic impact of generational trauma is not adequately identified in the research question and should be taken into account in the analysis i.e. “family history” is not sufficient. How will these social determinants of health be accounted for to avoid blame and shame on individuals and the community?
- The proposed research method needs to provide details of analysis and rationale for the sample size.
- Rationale for why this particular indigenous community was chosen should be provided to determine that the inclusion criteria are appropriate for the research question (TCPS2 4.1).
- Epidemiological issue: need a comparison population outside of the community for a comparator.
- When a researcher goes into any community to do epidemiological research, they need to identify and engage the local medical provider. Future ongoing care must be in place to provide follow-up care for participants (TCPS 2 Chapter 13).
- Biospecimen/genetic materials: the secondary and indefinite future use of this data needs to be addressed in the research agreement.

Recruitment:

- Is the Manitoulin Island health care centre an appropriate and safe place to be recruiting?
- What is the rationale for participants to be over 19 years of age (age of majority in Ontario is 18)?
- Inclusiveness: how are they engaging off-island/urban community members? Does the recruitment strategy capture everyone it is intended to capture? Does it exclude anyone unnecessarily (TCPS2 Chapter 4)?

- The use of sign-up sheets in a public meeting for recruitment does not allow for anonymity and may impact willingness to participate. It would be better if information was provided during the recruitment meeting and participants were given the option to contact the researcher privately at a later time to gain further information and express interest in participating. There is a risk of coercion both to participate and to not participate in such a public gathering (TCPS2 Articles 3.1, 9.6).
- Contact by telephone: the basic standard of living may be compromised for some Manitoulin Island participants and access to telephone cannot be assumed; recruitment/communication strategy needs to include an alternative form of communication that is used by the community (TCPS2 Article 9.8).

Confidentiality, Anonymity, and Privacy:

- If there is language barrier, how will it be addressed? Who will act as the interpreter; a community member? The interpreter would need to be fully apprised and agree to the research responsibilities relating to confidentiality and privacy, as any breach will violate a participant's rights.
- It is unclear if any research data will be collected from previous health records or just collected directly from the participant at the time of the intervention.
- Data should be stored securely at the community health center to protect confidentiality and privacy; all health information should be de-identified and coded (TCPS2 Articles 5.1, 5.2, 5.3). The research agreement and Informed Consent Form should reflect these provisions (TCPS2 Articles 5.2, 9.16).
- The research agreement should outline provisions for confidentiality and protection of the identity of the community (TCPS2 Articles 9.16, 9.20). Further, if the researcher proposes to compare findings to other communities, the communities may be identifiable (TCPS2 Articles 9.19, 9.22).
- The researcher should indicate if the 'key' that links identifiers to participants will be kept separately from the de-identified data or destroyed at some point.
- An indefinite retention period is stated, but no real justification is presented as to why the data will be kept indefinitely.

Consent Process/ Informed Consent Form (ICF):

- There needs to be a provision for participants to take the ICF away and consult with an elder or other member of the community (TCPS2 Article 3.2).
- For participants who are illiterate, or for those whom English may not be their first language, provisions should be made for translation (TCPS2 Articles 3.9; 4.1).
- For participants lacking capacity, if appropriate, an assent process needs to be established (TCPS2 Article 3.10).

- The rights of family members' wishes must be considered in regards to the future use of participants' biological materials (TCPS2 Articles 9.20, 9.21, 9.22). This should be addressed in the research agreement and ICF.
- When a researcher intends to transfer a participant's personal health information to the local health care provider, the researcher must first seek and obtain consent from the participant.

Risks and Benefits:

- There is physical risk with future use of biological specimens for genetic studies. The researcher needs to clearly outline in the research agreement, both for individuals and the community, how the risks will be mitigated in concert with OCAP™ principles (TCPS2 Articles 9.8, 9.19).
- Findings of a new health condition or diagnosis, or unanticipated incidental findings, may pose risk of social stigma for participants (TCPS2 Articles 3.4, 9.16, 9.17). How will this be addressed?
- There is potential risk for loss of privacy in a small community. Participants may be identified by their peers if it becomes known that a health status exists
- What medical supports will be provided if secondary/unanticipated health findings emerge? Are there ongoing resources for medical support? Have existing medical practitioners been informed? If follow up support is required how will it be coordinated?
- There is risk of information privacy and security with plans for indefinite data storage. Details for the complete data management plan from access to destruction should be provided.
- The "complete medical history and thorough physical examination" are indicated as benefits for participants. However, taking the medical history may actually cause psychological risk depending on what information is gleaned. What support will be available if participants become upset or distressed?

Dissemination:

- How will the participants and the community be informed about the research results (TCPS2 Articles9.17, 9.18)?
- Dissemination and publication of research results needs to be done in conjunction with the indigenous community and as agreed to in the research agreement (TCPS2 Articles 9.17, 9.18).