



# Exploring resources for ethical Indigenous engagement in clinical trials: Findings and recommendations for researchers to conduct clinical trial research in good way

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# Land Acknowledgement

I acknowledge that I live, work, and play on Treaty 6 Territory and the Homeland of the Métis. I pay my respects to the First Nations and Métis ancestors of this place and reaffirm our relationship with one another.

# Introduction & Background

- Underrepresentation of Indigenous communities in clinical trials <sup>(1)</sup>
- Clinical trials often fail to respect Indigenous principles of self-determination and sovereignty <sup>(2)</sup>
- Past unethical research practices, along with the effects of colonization, geographical isolation and discrimination, have led to the loss of sovereignty over lands and culture <sup>(3)</sup>
- Reluctant to participate due to historical mistrust <sup>(2,3)</sup>
- Current strategies include community-based participatory research, building trusted relationships and incorporating traditional healing practices alongside Western medical approaches <sup>(4,5)</sup>
- Need to strengthen community partnerships through long-term meaningful relationships by involving Indigenous community members in **research design, implementation and dissemination** <sup>(5,6,7)</sup>
- To ensure their voices are heard at every step of the research process <sup>(6)</sup>

# Objectives

To identify wise practices for Indigenous engagement, leadership, and participation in clinical trials

To interview researchers and knowledge holders affiliated with SPOR (the Strategy for Patient-Oriented Research) support units and their networks about ethical/wise practices that should be undertaken when engaging with Indigenous communities in clinical trials

To identify approaches of integrating Indigenous ways of knowing, doing and being into clinical trials research

To gather insights on current practices, challenges faced and future recommendations that aim to enhance the involvement of Indigenous communities in clinical trials in a respectful and meaningful manner

# Methods

## Needs assessment

### Literature search

- Gathered the existing literature on strategies/principles that the researchers use and implement when they connect with Indigenous communities in clinical trial research
- Assessed the findings from available literature, identifying key themes and wise practices for Indigenous health research

### Individual interviews

- Conducted virtual interviews via Zoom with knowledge holders on their approaches to engaging with Indigenous communities in clinical trials
- Identified current practices, challenges faced and future recommendations for effective Indigenous clinical trial engagement

# Common themes from literature search

Building and maintaining a respectful trusting relationship

- **Transparent and open communication** with community members and Elders
- **Collaborative partnership** to hear more Indigenous voice
- Determining **community interests and willingness** to participate

Approaches that are culturally adapted, grounded, or promote a 'culture as health' approach

- Indigenous involvement to **design and lead culturally appropriate studies**
- **Cultural humility**
- **Community ethical approval** as a crucial component of self-determination and sovereignty

Enhancing representativeness in clinical trials through strategic inclusion and diversity initiatives

- **Targeted and culturally competent recruitment**
- Reimburse costs, **virtual follow-up** and offering flexible clinic hours
- Equitable access to **training, funding, mentorship and advancement** opportunities

# Guiding questions: one-on-one interviews

1) What existing resources are available for Indigenous engagement in clinical trials, and are these adequate or appropriate?



2) What are the challenges or barriers you think a researcher will face in the upcoming years who is planning to engage in clinical trials with Indigenous communities?



3) What are your recommendations for supporting the participation of Indigenous communities and people in research being done in good ways (for and with the communities)?

# Common themes from interviews

## Barriers to Indigenous engagement

- Limited **funding resources**: disparities between needs and support
- Lack of a **national process** for culturally safe engagement
- Feeling of **exclusion**: not giving them the opportunity to make decisions

## Indigenous Data Sovereignty and OCAP principles

- Adhere to **OCAP** (ownership, control, access, possession) principles
- Being recognized as **co-authors** to own their data
- Indigenous voices: **involvement, perspectives and needs** in the research process

## Trust and meaningful community representation

- Building **strength-based collaboration**
- Inclusion of **younger people**: traditional and historical knowledge
- **Mutually beneficial research**: academic interests and community needs



# Summary of findings

Strong, respectful  
relationships with  
transparent  
communication

Indigenous Data  
Sovereignty

Culturally competent  
approaches

Adequate funding  
resources from  
government

Future growth and  
capacity building

# How can we improve trial participation

- By modifying rigid inclusion and exclusion criteria
- Consider study duration and location
- Increasing flexibility in protocols and governance
- Study materials are culturally relevant and easy to read
- Reflecting on the characteristics of the trial teams
- Research includes outcomes that are valued by Indigenous people

# Deliverables

- Complete behavioural ethics application
- Participant's data collection form/ questionnaire
- Develop a general consent form
- Project report summarizing key findings

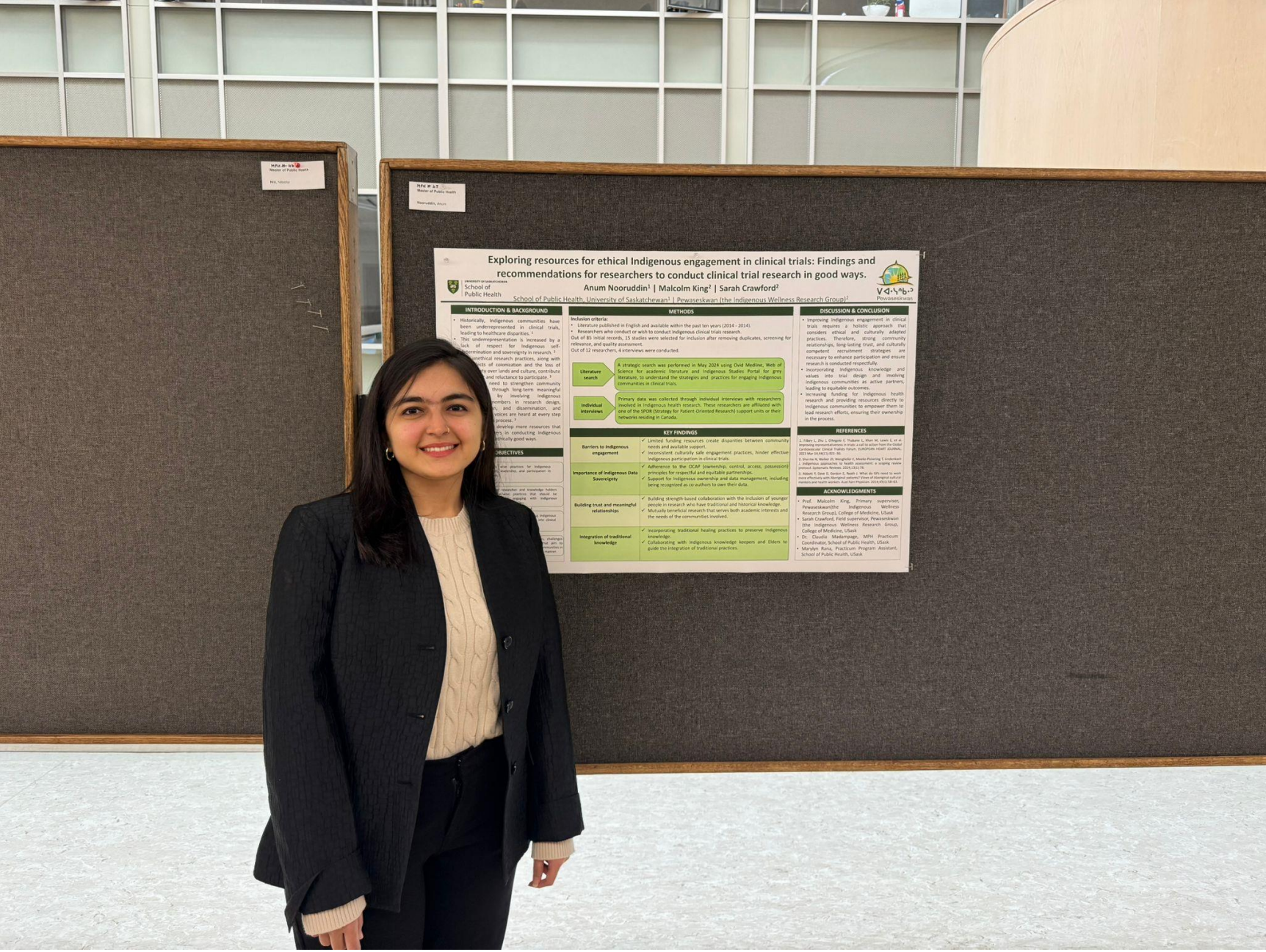
# Discussion & Conclusion

- Limited sources indicated the need to identify ethical and respectful ways of engaging Indigenous communities in clinical trials.
- Strong partnerships between researchers and Indigenous communities improve equity and patient engagement. <sup>(4)</sup>
- The findings highlight the need for enhanced funding and the inclusion of Indigenous voices throughout the research process to ensure that research is ethically conducted.
- Effective communication requires transparency, cultural sensitivity, and strength-based approaches.

# Limitations

- Indigenous underrepresentation in clinical trials is overlooked, with limited literature on effective engagement, hindering strategy development.
- Clinical trials often lack Indigenous participation during the design and implementation phases, leading to interventions that are not culturally adapted to Indigenous ways of knowing and doing. <sup>(8)</sup>
- Lack of available resources, unfamiliarity with research, problems with research materials and loss of follow-up create barriers to participation. <sup>(8)</sup>
- Research subjects are sometimes recruited through snowball sampling, which may include bias and affect validity.





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Thank you!

Any questions

