AT A DISTANCE: CHANGING AND ADAPTING RESEARCH PRACTICES ETHICALLY DURING A PANDEMIC

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OBJECTIVES

When conducting research at a distance:

- Identify means to operationalize ethical principles
- Gain an appreciation of best ethical practices
- Be cognisant of the ongoing need to protect research participants and promote their well being

OUTLINE

- The Pandemic Research Context
- The Consent Process
- Collecting Data
- Data Storage
- Compensation
- Potential Psychological Risks
- Research Ethics Boards
- Summary
- Resources

THE PANDEMIC RESEARCH CONTEXT

Scope of the presentation:

Applies to:

- Research studies falling **outside** Health Canada's jurisdiction

  For research studies falling under Health Canada's jurisdiction other practices must be followed:

  "Interim Order respecting clinical trials for medical devices and drugs relating to COVID-19"

- Research practices involving virtual or telephone interaction
  - Includes recommendations for best ethical practices

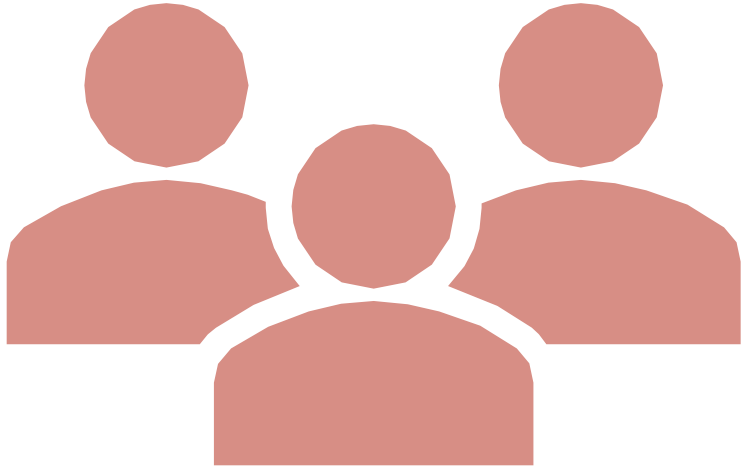
THE PANDEMIC RESEARCH CONTEXT (CONT'D)

Immediate need to:

- Adapt long standing ethical research practices
- Protect

  Research participants and promote their well-being
- Assist

  Researchers and members of the research team



Evidently, we must adapt our research practices

THE PANDEMIC RESEARCH CONTEXT (CONT'D)

THE PANDEMIC RESEARCH CONTEXT (CONT'D)

"Les activités de recherche pouvant se faire à distance..."

"Pour les recherches impliquant des participants humains, les contacts téléphoniques ou virtuels avec les participants devraient être privilégiés."

Pierre Lafleur

Le sous-ministre adjoint, MSSS, Québec, le 5 juin 2020

THE CONSENT PROCESS

"Certain types of research require alternate processes for seeking consent…. researchers may request an **alteration to consent** requirements…. these include a requirement to satisfy the research ethics board (REB) that it is impossible, impracticable …. or inappropriate to address the research question without the requested alteration…REBs must consider whether the requested **alterations are justified** or whether another approach would make it possible, practicable and appropriate to follow the normal consent requirements."

(TCPS2 2018, Chapter 3, Introduction)

THE CONSENT PROCESS (CONT'D)

"Consent to care not required by a person's state of health, to the alienation of a part of a person's body, or to research that could interfere with the integrity of his person **shall be given in writing**.

However, consent to such research may be given otherwise than in writing if justified in the circumstances in the opinion of a research ethics committee. In such a case, the committee determines the proper manner, for evidential purposes, of obtaining consent.

It may be withdrawn at any time, even verbally."

art 24 CCQ

CONSENT PROCESS

"Consent encompasses a process that begins with the initial contact **(e.g., recruitment)** and carries through to the end of participants' involvement in the project."

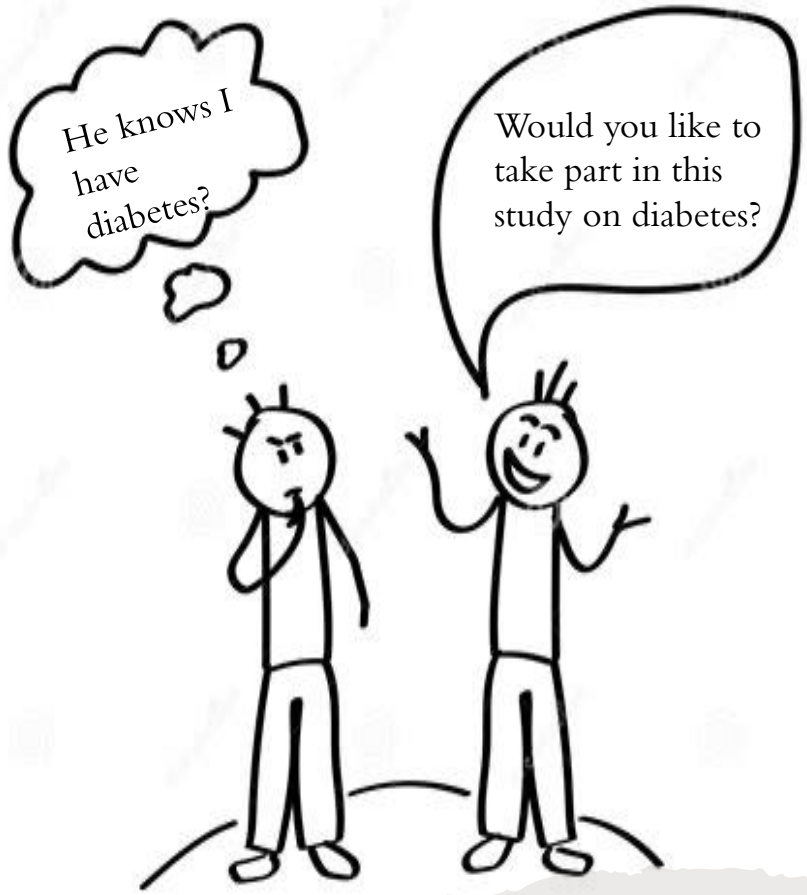
(TCPS2. 2018, Art. 3.3)

THE CONSENT PROCESS (CONT'D)

Recruitment Strategy

"Initial contact with individuals about a research project should be made by someone that individuals would **expect** to have relevant information about them, or in other ways that do not inappropriately intrude on their life or privacy"

(CIHR Best Practices for Protecting Privacy in Health Research, 2005)



THE CONSENT PROCESS (CONT'D)

Determine:

- **WHO** makes initial contact with potential participants (respecting the voluntariness principal)
- **WHAT** method can be used to contact potential participants (in person, virtually or telephone)
- **WHEN** potential participants are contacted (in person, virtually or by telephone)
- **HOW** potential participants' contact information will be shared, securely with the research team (secure institutional e-mail, special access to upload the list on a secure server)

THE CONSENT PROCESS (CONT'D)

The person delegated to obtain consent:

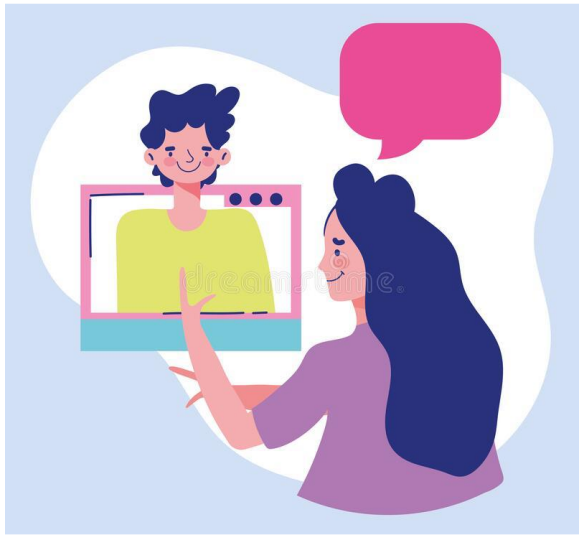
- Contacts the potential participant and provides more information and sends by email or postal mail:
  - A copy of the consent form
  - A virtual or telephone meeting date and time
    - Includes a password link for the virtual meeting

THE CONSENT PROCESS (CONT'D)

The Information and Consent Form

- Include information about:
  1. The procedures for obtaining informed consent:
     Specify whether by telephone or virtually or whether the participant has a choice
     - Name the App (e.g., TEAMS), if using
     - Indicate consent will be recorded
  2. The procedures for collecting data
     - Name the App (e.g., TEAMS), if using
     - Indicate that data collection procedures (e.g., interview) will be recorded

THE CONSENT PROCESS (CONT'D)



On the virtual or telephone meeting date:

- Explain all aspects of the study
- Ensure understanding
- Provide time to reflect on the information received and encourage questions
- If the potential participant requests more time to reflect on the decision to participate, schedule a second meeting

THE CONSENT PROCESS (CONT'D)

Informed Consent Discussion Checklist

- ☑ I explained all aspects of the study in simple language
- ☑ I explained the study in the language the participant understands
- ☑ I used an interpreter because the participant spoke _____
- ☑ I verified understanding
- ☑ I provided time to reflect on the information received
- ☑ I encouraged the participant to ask questions
- ☑ I scheduled a second meeting, if the potential participant requested more time to reflect on the decision to participate

THE CONSENT PROCESS (CONT'D)

Begin Recording

Once the consent discussion is completed and potential participant agrees to take part in the study

BEGIN recording verbal informed consent

THE CONSENT PROCESS (CONT'D)

Recording verbal informed consent from vulnerable participants

- <u>Do not record consent from:</u>
  - Persons whose names should not be documented (e.g., placed in legal jeopardy)
- <u>Record consent from</u>:
  - Legally authorized representatives

    For minors and mentally incapacitated adults
- <u>Record assent from</u>:
  - Actual participants **to the extent minors and mentally incapacitated adults are capable of doing so**

*Research Ethics Board approval is required for all consent procedures

THE CONSENT PROCESS (CONT'D)

Optimizing confidentiality

- Obtaining verbal consent virtually
  - No visual recording
  - Ask participants to close their camera

- Obtaining verbal consent by telephone
  - Use a separate recording device
  - No audio or visual recording on personal phones
  - Activate "private number" if using personal phones

THE CONSENT PROCESS (CONT'D)

Read and Record

Ask the participant to read:

PARTICIPANT STATEMENT OF CONSENT

I understand the information that was explained to me as contained in this consent form. All my questions were answered to my satisfaction. I will be sent a confirmation indicating that I agreed to take part in this study. My participation is voluntary, and I can withdraw from the research study at any time without any consequences and without having to give a reason. Withdrawing from this research study, at any time, will not affect my medical care now, or later, in any way (where applicable). By agreeing to take part in this study, I do not give up any of my legal rights. I agree to take part in the study "….." (specify the study title).

THE CONSENT PROCESS (CONT'D)

Continue recording	Ask the participant to clearly state their **full name** and the **date**
Read and Record	Read a Researcher Statement *I, as the person obtaining consent, certify that I have explained to the participant or their legal representative (where applicable) the research study information and have answered all questions. I have clearly explained that the participant is free to withdraw at any time without providing a reason, and without any consequences. I commit, together with the members of the research team to respect all conditions described in this consent form.*

THE CONSENT PROCESS (CONT'D)

Continue recording	As the person obtaining consent, **state your name and the date**
Stop recording	
Send	Send a **confirmation** to participants that they gave informed consent verbally by email or postal mail.

THE CONSENT PROCESS (CONT'D)

"Where consent is not documented in a signed consent form, researchers may use a range of consent procedures, including oral consent, field notes and other strategies, for **documenting the consent process.** " (TCPS2, 2018, Art. 3.12)

- Documenting verbal informed consent:
  - Demonstrates transparency
  - Creates an audit trail

THE CONSENT PROCESS (CONT'D)

Tools to Document Verbal Informed Consent:

- Informed Consent Discussion Checklist
- Verbal Consent Recording
- The Consent Log

THE CONSENT PROCESS (CONT'D)

Consent Log-Sample

JOURNAL DE CONSENTEMENT ÉCLAIRÉ DES PARTICIPANTS

Titre du projet:

Numéro identificateur du CÉR:

Nom	Accepte ou refuse de participer	Méthode (virtuelle, téléphone)	La date de l'enregistrement du consentement	La personne qui a obtenu le consentement	La date le fichier d'enregistrement du consentement verbal a été téléchargé	Le chemin d'accès du fichier.	Commentaires

THE CONSENT PROCESS (CONT'D)

WRITTEN AND VERBAL CONSENT

- Written consent – formalized method

  When participants actively sign a consent form they become more aware of study requirements and their involvement (Standards du FRSQ sur l'éthique de la recherche en santé humaine et l'integrité scienifique, 2008, Art. 19)

- Verbal consent – more prone to be viewed with mistrust and suspicion
- USE ADDITIONAL TOOLS TO DOCUMENT VERBAL CONSENT
  - Prudent
  - Warranted

DATA COLLECTION

Surveys
Questionnaires
Interviews
Focus Groups
Etc.

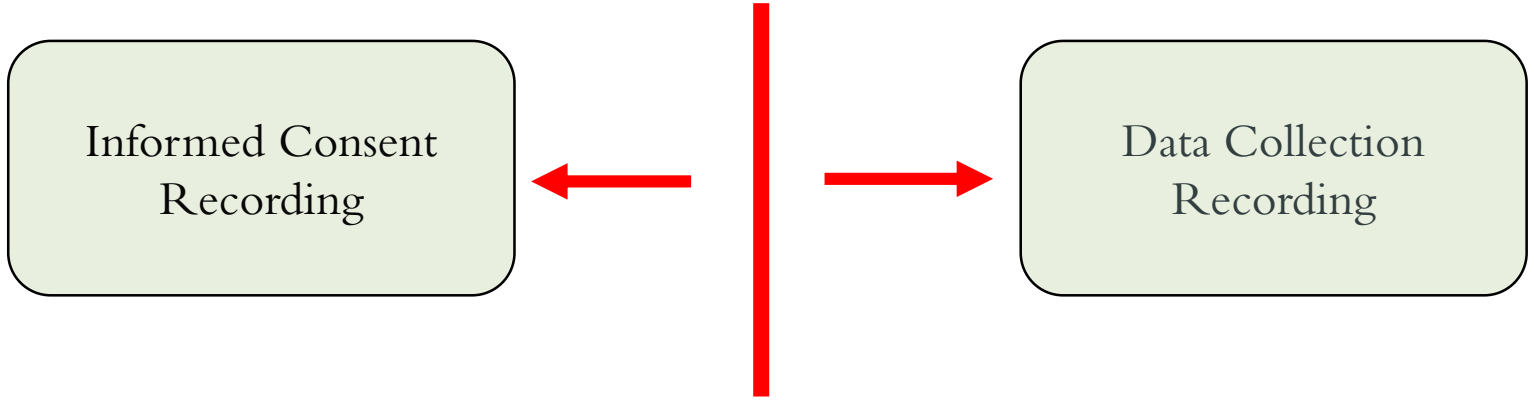
To begin data collection, ensure the recording was **STOPPED** after obtaining informed consent

- When study procedures are initiated, restart recording

DATA STORAGE

Once data collection is complete:

- Create two separate electronic files for each participant
  - One for the informed consent recording
  - One for the data collection recording



Without exception, separate informed consent recordings from other study data

DATA STORAGE (CONT'D)

Store	Store all participant verbal informed consent recordings collectively in **one** separate folder
Ensure	Ensure the folder is protected by a **unique password** and held on a secure server
Keep	Keep the data collection recordings **separate** in another folder with a different password held on a secure server

DATA STORAGE (CONT'D)

Comparable strategies to store data securely

Traditional signed paper copies in a *locked* cabinet.

VERSUS

Storing the electronic file recordings of verbal informed consent

DATA STORAGE (CONT'D)

"Privacy risks arise at all stages of the research life cycle, including initial collection of information, use and analysis to address research questions, dissemination of findings, storage and retention of information, and disposal of records or devices on which information is stored." (TCPS2, 2018, Ch.5)

Ensure best practices!

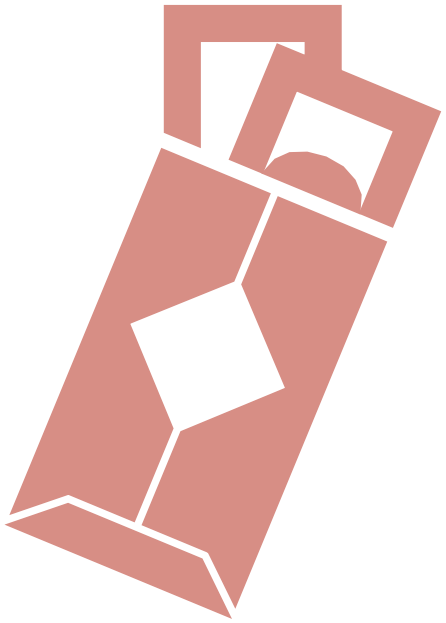
DATA STORAGE (CONT'D)

Are the tools and methods you use highly secure?

- Ensure that all apps are approved by your Research Ethics Board and institution
- MSSS directive:
  "TEAMS" only

  "ZOOM" no longer acceptable within the Health and Social Services Network
- Data Sharing Agreements

COMPENSATION



If compensation is offered, how will it be sent?

- Gift card
  - Email, postal mail
- Checks
- E-transfer
- Etc.

POTENTIAL PSYCHOLOGICAL RISKS

"Harm is anything that has a negative effect on the welfare of participants, and the nature of the harm may be social, behavioural, **psychological,** physical or economic." (TCPS 2, 2018, B.)

- Monitor participants as you would in-person, but it may be more challenging
- Develop strategies in anticipation of these challenges

POTENTIAL PSYCHOLOGICAL RISKS (CONT'D)

A participant demonstrates signs of distress during an interview or when a questionnaire is administered over the phone or virtually.

How should this situation be managed?

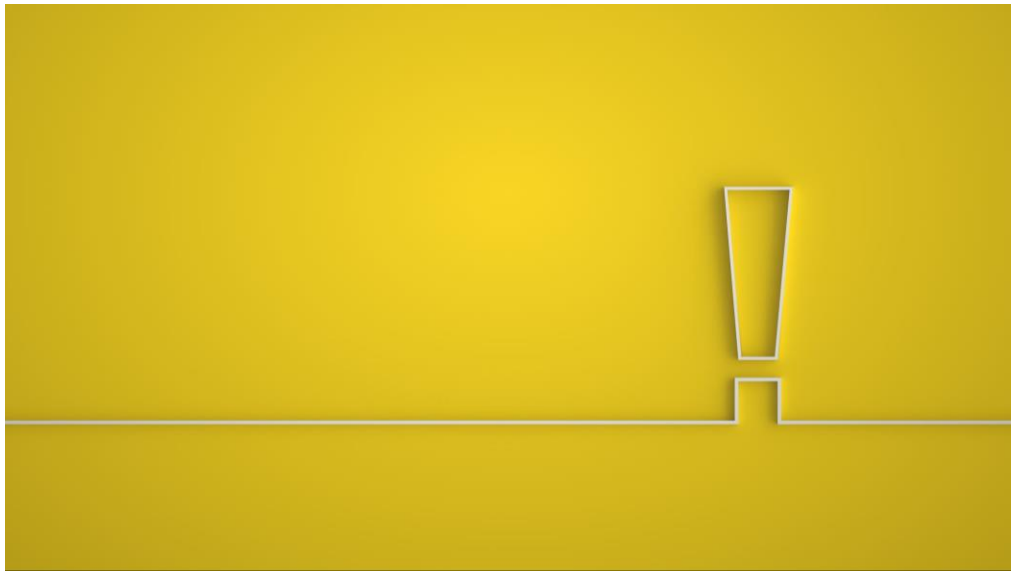
POTENTIAL PSYCHOLOGICAL RISKS (CONT'D)

Interviews and questionnaires

Ascertain the level of distress to determine the appropriate type of response

Examples:

- Skip a question
- Take a break
- Withdraw from the study
- Accompany and refer to an appropriate resource
- Take immediate action (emergency)



POTENTIAL PSYCHOLOGICAL RISKS (CONT'D)

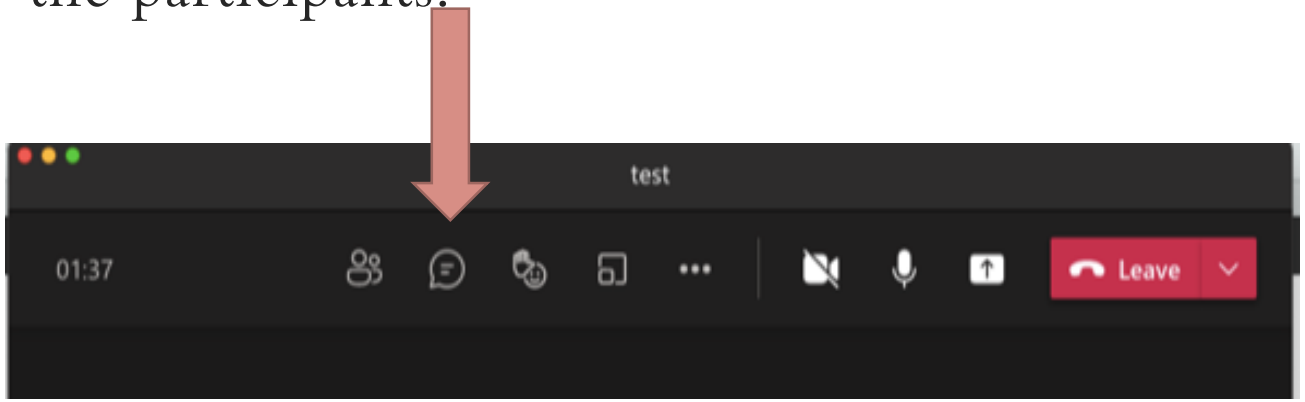
A participant demonstrates signs of distress during a virtual focus group discussion.

How should this situation be managed?

POTENTIAL PSYCHOLOGICAL RISKS (CONT'D)

Focus group discussions

- Requires the presence of two facilitators
  1. If participant appears distressed, one of the facilitators contacts the research participant **privately** using the chat feature or by telephone.
  2. Once the participant is contacted then the researcher can attend to the participants.



POTENTIAL PSYCHOLOGICAL RISKS (CONT'D)

Depending on the topic sensitivity

- Emotional distress may be more difficult to detect at a distance
- Symptoms may only appear after study procedures are completed

Err on the side of caution

Follow-up phone calls are encouraged

PRIORITIZE THE SECURITY AND SAFETY OF PARTICIPANTS

RESEARCH ETHICS BOARDS

Research Ethics Boards (REBs) must approve all methods and procedures

The methods and procedures in this presentation serve only as examples

Research Ethics Boards (REBs) are empowered to:

Approve, modify, stop or reject studies and amendments in accordance with ethical principals and legal requirements

Information and justification:

- Include **detailed information** about all methods/procedures
- Provide a **justification** for the use of these methods/procedures
  - E.g., Recruitment strategies, the informed consent process, data collection, data storage, compensation, protocols for mitigating risk, etc.
- Submit an amendment for needed changes to an ongoing study

RESEARCH ETHICS BOARDS (CONT'D)

Researchers may face unexpected and unprecedented challenges

Research design

Study conduct

Consult your Research Ethics Board (REB) for support

The REB can:

- Advise on the information the REB requires to conduct its review
- Provide guidance to avoid needless delays for both the researchers and the REB

SUMMARY

- Extraordinary times push us to adapt our research practices

  Recruitment strategy, Consent process, Data collection and storage, Compensation, Data Storage, Mitigating psychological risk

- The core ethical principles that support best ethical practices remain the same

  - Only the manner they are operationalized may differ

Research ethics review (cont'd)

Operationalizing Ethical Principles

Respect for Human Dignity		
Respect for Persons	Concern for Welfare	Justice

(TCPS2 2018)

RESOURCES (CONT'D)

- MSSS: Éthique de la recherche
  https://msss.gouv.qc.ca/professionnels/ethique/ethique-de-la-recherche/

- Ethical Conduct for Research Involving Humans Canadian Institutes of Health Research Natural Sciences and Engineering Research Council of Canada Social Sciences and Humanities Research Council of Canada, 2018
  http://www.pre.ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2018.html

Thank You!

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