

GUIDELINES

Ethical Considerations Related to Projects Involving Direct Interaction with Participants during the COVID-19 Pandemic

Who is this for?

Project staff who will conduct evidence-generating projects involving direct interaction with human participants. Project staff include Public Health Ontario (PHO staff) and public health unit (PHU) staff where the PHU appoints PHO as their board of record.

Direct interaction can involve remote and/or in-person methods of participation and can include the following: one-on-one interviews, focus groups, participant observation and the collection of human-derived specimens.

Background

The purpose of this document is to assist project staff in the planning and preparation of project submissions to PHO's Ethics Review Board (PHO ERB) during the COVID-19 pandemic. These guidelines should be used in conjunction with the [Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – TCPS 2 \(2018\)](#).¹

During the COVID-19 pandemic, additional project-attributable risks can arise when conducting projects that involve direct interaction with participants. Assessment of the ethical acceptability of such projects will therefore require a greater emphasis on the safety and well-being of project participants, project staff, and the general public. As in all research, however, it is important to strike a balance between the potential benefits of research and the protection of participants because curtailing research unnecessarily can deprive society of important scientific knowledge.

Ethical assessment of new projects or resuming a previously-approved project will be done in conjunction with [local public health authority directives and precautions](#) and institutional workplace guidelines.² It is the responsibility of the project lead to be aware of public health safety precautions (e.g., personal protective equipment [PPE], physical distancing, and mandatory face coverings) and to ensure that these measures are appropriately planned for and implemented.

Ethical Considerations

Project Risks

The ethical acceptability of a project depends on weighing the foreseeable risks of the project against its potential benefits. However, the evolving COVID-19 pandemic has changed the concept of minimal risk (i.e., the risks associated with everyday life) in the context of projects involving any in-person interaction with participants. For example, projects involving direct face-to-face interaction that would typically be classified as “minimal risk” are now considered “high risk” due to the risk of exposure to the SARS-CoV-2 virus.

This section describes additional project-attributable risks that can arise in the COVID-19 environment when conducting projects that involve direct interaction with participants, either **in-person** or **remotely**. For more information on additional project-attributable risks during COVID-19, refer to the [TCPS 2 COVID-19 Interpretations](#).³

Project teams should consider these additional risks when assessing the overall risk of their project and when completing [PHO's Risk Screening Tool \(RST\)](#).⁴

NEW RISKS ARISING FROM REMOTE PARTICIPATION METHODS

- In an effort to adhere to public health precautions such as social distancing and to limit risks related to physical contact (i.e., transmission of disease), project teams are changing their project plans and using remote participation methods instead of in-person. Remote participation will be the preferred approach, and the PHO ERB will recommend that project teams use methods eliminating in-person contact.
- Project teams should consider the ethical risks related to privacy, confidentiality and security when using remote methods such as phone, online platforms (e.g., email, web-based surveys) or virtual platforms (e.g., Zoom, Skype) when collecting data and when sharing findings with participants. For example, it may be difficult for a participant to secure a private space within their home to conduct an interview, personal email may not be the most secure method of transferring sensitive or personal information, and anonymity cannot always be guaranteed when using virtual platforms.
- Online and virtual platforms that can ensure the security of information collected (e.g., encryption) should be used. Project teams should consult with their institutional privacy advisors for further guidance regarding the appropriate use of these platforms.
- Remote participation can also introduce ethical issues related to fairness and equity, where only those with sufficient access to resources (e.g., internet, computers and phones) can participate, thereby effectively excluding certain groups (i.e., low socio-economic populations). For more guidance on ethical issues related to fairness and equity, refer to [Chapter 4 of the TCPS 2](#).¹

NEW RISKS THAT EMERGE FROM IN-PERSON PARTICIPATION METHODS

Remote participation is the preferred approach. This section applies where in-person participation cannot be avoided.

- In-person interaction with participants can lead to risks of increased participant exposure to the COVID-19 virus. In addition, project teams need to consider the societal risks of further transmitting the virus beyond individual participants to others, including to non-project team staff and family members.
- Risk of exposure will depend on the location/setting of the project as well as current COVID-19 infection rates. Project teams are therefore responsible for being aware of the risk of exposure in the geographical region (e.g., [Public Health Unit](#), neighbourhood) and type of location where interaction with participants or other data collection will occur.⁵ For example, certain types of settings such as long-term care homes and hospitals are considered high-risk exposure settings. Similarly, as COVID-19 infection rates rise within a region, so does the general risk of exposure.
- Depending on the location of the project (e.g., university, public or private school, harm reduction clinic, hospital) participants may be required to adhere to COVID-19 screening and assessment protocols. Project teams should notify potential participants of such protocols as well as the implications of their results on eligibility to participate. For example, an individual may not be able to participate if they exhibit symptoms or if the screening reveals that they have been exposed to COVID-19.
- It is strongly recommended that participant contact information be collected to facilitate contact tracing efforts by public health officials in the case that a participant or project team member tests positive for COVID-19. Participant contact information should be stored separately from any project related data. Project teams should also notify potential participants that their anonymity cannot be guaranteed for this reason, and of the potential for information to be disclosed to public health officials if required.
- Ensuring participant privacy in public spaces can be challenging when trying to maintain physical distancing measures (e.g., maintaining two meters between project staff and participant and speaking through masks). Project teams should notify potential participants of this risk and strive to find alternative approaches that do not require in-person interaction in public settings.
- Participants may be asked to travel to a project location or setting. Risk of exposure while taking public transit (e.g., buses, taxis, Lyft, Uber) should be considered and participants should be reminded to take all required precautions (e.g., wear a mask), [based on local public health restrictions](#).⁶
- Project teams are required to follow the cleaning protocols of the project location/setting. If hand sanitizer and face coverings are not available, project teams are required to provide these for participants.

- If physical distancing cannot be maintained or the project requires direct physical contact (e.g., collection of biological specimens, physical measurements), project teams are responsible for ensuring that appropriate and adequate personal protective equipment (PPE) is available for both project staff and the participant.

NEW RISKS ARISING FROM CHANGES TO PARTICIPANTS' PERSONAL CIRCUMSTANCES

Due to the nature of pandemics, the existing circumstances or factors that can increase an individual's vulnerability to certain risks may be exacerbated. Particular individuals or groups may be more likely than others to experience a harm to their interests or welfare, or more likely to experience it to a greater degree. For example, immunocompromised individuals are at greater risk of morbidity and/or mortality if participating in a project increases their exposure to the virus. Similarly, individuals living with a mental health illness are at greater risk when participating in a project investigating subjects such as suicide or self-harm due to the additional stress and isolation they may be experiencing as a result of the pandemic.

Project teams will need to pay greater attention to a participant or community's vulnerable circumstances when assessing project risks in a COVID-19 context. The following types of circumstances or factors that increase a participant's vulnerability to certain risks should be considered:

(The following list of factors was adapted from the [University of Toronto's Guidance for the Recovery of Human Research during the COVID-19 Pandemic](#))⁷

Physical/physiological:

- Greater risk of morbidity and/or mortality due to age, pre-existing medical conditions, immunocompromised status, etc.

Psychological/emotional:

- Existing mental health issues including substance use
- Individuals with exacerbated mental health and addiction issues due to [pandemic directives and precautionary measures](#) (e.g., isolation, subjective fears)⁸

Social:

- Factors that put individuals at greater risk of exposure, or factors that create barriers to obtaining knowledge for prevention, taking preventative measures, obtaining treatment, and/or being able to maintain the health and life of others in their household or community (e.g., lack of space, food and water insecurity, unemployment, poverty, dependents, limited access to critical health and social services, stigmatization)

Informed Consent Process

Project protocol modifications may be required as a result of changes in public health directives and recommended precautions. If these changes impact interactions with participants or constitute a substantive change in project design, project teams have an ongoing duty to provide participants with all information relevant to their ongoing consent to participate in the project ([TCPS 2, Article 3.1](#)).¹ Participants should therefore be notified of any changes to the following:

- project-related risks
- data collection methods (e.g., transitioning to remote participation instead of in-person)
- project location
- local public health directives and precautions (e.g., COVID-19 screening protocols, collection of personal information for contact tracing, mandatory face covering)
- the possibility of project postponement
- project design (e.g., sample size, participation criteria)

Participants should be given the opportunity to re-consent if needed, not only because of the substantial project changes but also to consider any changes in their personal circumstances that may prevent them from participating.

Consent Form Documents: COVID-19 Wording

(The following information was adapted from the [University of Toronto's Guidance for the Recovery of Human Research during the COVID-19 Pandemic](#))⁷

The information below should be included, as relevant, throughout the consent form.

- The project site is located [insert], under the jurisdiction of [public health unit name]. We are taking all safety precautions to reduce the risk of spread of COVID-19 and expect you to follow public health directives as well.
- If you think your personal circumstances (e.g., age, immuno-compromised), might increase the risks associated with your participation, please speak with the project team before deciding to participate. You are under no obligation to participate and you are free to change your mind at any time about participating in the project.
- The location of the project requires that the following safety protocols be followed:
 - All persons entering the premises are required to have a COVID-19 screening assessment. Depending on the results of your assessment, you may be asked to leave the premises.
 - Take [appropriate precautions](#) (e.g., wear a mask) if taking public transportation and entering public indoor spaces.⁶
 - Wash your hands upon entrance to any building or indoor space. Hand sanitizer will be made available to you.

- Physical distancing will be maintained at all times, and if not possible, wear a face covering. Appropriate PPE will be provided as needed.
- We will be collecting personal contact information that we must retain in order to follow up with you and/or conduct contact tracing if you may have been exposed to COVID-19 by coming to the project site.
- Contact information will be kept separate from data collected through the project to allow for de-identification of the project data (if applicable).
- You maintain your right to withdraw from the project at any time, including project data (if applicable). If you do withdraw, we will continue to retain your contact information and will only share it if required for contact tracing.
- We cannot guarantee anonymity as your personal contact information identifies you as a participant.
- As the COVID-19 situation continues to evolve and infection rates fluctuate, please be aware that the project may need to be changed or postponed if the risk of exposure increases. The project team will notify you immediately of any changes, and you may be required to re-consent if necessary.

Procedures for Approval of Projects during COVID-19

Process

Since the COVID-19 context continues to rapidly evolve, risk to exposure of the virus should be regularly monitored as well as any changes to local public health authority directives and precautions. PHO's ERB will decide on the ethical acceptability of a project in accordance with a proportionate approach to research ethics review ([TCPS 2 Article 6.16](#)) and the evolving COVID-19 context.¹

In some cases, the risks may be too high to justify the benefits, and project teams may be required to adjust their project plan to lower risk to participants (e.g., transition from in-person to remote participation methods) or postpone a project until the risk of exposure to the COVID-19 virus decreases.

Projects involving in-person interaction may be temporarily suspended if PHO's ERB deems the current overall risk of exposure to be too high. Please refer to ongoing updates on the Ethics Services webpage as new information about COVID-19 emerges.

If temporary suspension of an active project will disrupt participant involvement or potentially result in harm to participants, please contact the [ethics office](#) to discuss approaches to minimize and mitigate any harms.

Submission Requirements

RECOVERY OF PREVIOUSLY-APPROVED PROJECTS

Projects that have already been approved that involve direct interaction with human participants must submit an amendment to PHO's ERB for review and approval. The amendment is required to ensure that project teams have accounted for the COVID-19 context.

The TCPS 2 requires review and approval of project protocol modifications prior to implementation *"except when necessary to eliminate an immediate risk(s) to the participants"* ([TCPS 2 Article 6.16](#)).¹ When changes are implemented immediately to eliminate risk, PHO's ERB must be notified of the change within five business days.

The amendment should adhere to this guideline document and must include the following:

- a PHO Amendment Form
- a newly-completed [PHO Risk Screening Tool](#),⁴ and
- revised project materials including consent forms, PHO ERB application form, recruitment materials

After COVID-19 infection rates have dropped to a sufficiently low level, and provincial restrictions allow resuming safe in-person interaction with participants, an additional amendment should be submitted to the PHO ERB, including revised project materials (as listed above) describing any reinstated or revised procedures to be implemented after resuming interaction with participants. The ERB will make the final decision on the acceptability of the proposed amendment and whether the project activities can be safely resumed within the specific context and circumstances of each project.

NEW PROJECTS

Projects that involve direct interaction with human participants will follow regular submission requirements. To ensure that the COVID-19 context has been considered, submission materials must adhere to this guideline document.

References

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7. University of Toronto, Division of the Vice-President, Research & Innovation. U of T guidance for the recovery of human research during the COVID-19 pandemic [Internet]. Toronto, ON: University of Toronto; 2020 [modified 2021 Mar 22; cited 2021 Apr 05]. Available from: <https://research.utoronto.ca/covid-19-research-innovation-updates/u-t-guidance-recovery-human-research-during-covid-19-pandemic>
8. Canadian Psychological Association. "Psychology works" fact sheet: psychological impacts of the coronavirus (COVID-19) [Internet]. Ottawa, ON: Canadian Psychological Association; 2020 [cited 2021 Apr 05]. Available from: <https://cpa.ca/psychology-works-fact-sheet-psychological-impacts-of-the-coronavirus-covid-19/>

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For Further Information

For any questions or concerns related to the information in this guidance document, please contact PHO Ethics Services at ethics@oahpp.ca.

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