Emerging Ethical Issues Related to Research Conduct During COVID-19

Section 1: General Principle

The COVID-19 pandemic has altered research conduct significantly. Researchers are faced with converting studies involving in-person contact into remote methods of data collection due an elevated risk of exposure to the virus during any direct contact activities and to abide by Public Health and government directives of physical distancing (2 meters apart). During the initial stages of the pandemic, many studies were temporarily suspended at the University if data collection procedures could not be converted into remote methods of data collection.

As the government restrictions begin to relax, researchers are faced with new challenges related to emerging ethical issues and risks while conducting research during the COVID-19 pandemic. In particular, the concept of **"minimal risk"** as defined by the Tri-Council Policy Statement 2 (TCPS2) must be re-considered. Chapter 2 of TCPS2 defines **"minimal risk"** as **"research in which the probability and magnitude of possible harms implied by participation in the research are no greater than those encountered by participants in those aspects of their everyday life that relate to the research."** From the start of the pandemic, Public Health and the Provincial Government directives included staying home or working from home if possible, in order to minimize the transmission of the virus. While the TCPS2 definition of minimal risk has not changed, the pandemic has changed an entire population's daily circumstances. This means that each potential study participant's evaluation of minimal risk is not the same as what it once was. As a result, **the REB has deemed that the threshold for everyday minimal risk exposure related to in-person research has changed resulting in new ethical requirements for conducting research during a pandemic.**

It is important to note that research that can feasibly and safely be conducted remotely without significantly compromising the ethical standards and maintenance of confidentiality, should continue to be done remotely.

Section 2: Consent and Re-consent

All REB submissions (new studies or previously approved studies) require researchers to state in plain language in the consent form "all reasonably foreseeable risks and potential benefits, both to the participants and in general, that may arise from research participation" (TCPS2, Article 3.2c). When describing the foreseeable risks and potential benefits to study participants, researchers must clearly distinguish between the risks that are attributable to the research, and the risks to which participants would normally be exposed (TCPS2, Article 2.10). In other words, are you exposing study participants to an increased risk compared to their everyday comings and goings? In addition, consent discussions with study participants must **emphasize the voluntariness of consent** and that participation in a research study is **optional and not mandatory** (TCPS2, Chapter 3).

For previously approved studies where data collection on study participants is on hold, the researcher has an **ongoing ethical and legal obligation** to bring to participants' attention any changes to the research project that may affect them. These changes may have ethical implications that are germane to their **decision to continue research participation**, or may be relevant to the particular circumstances of individual participants (TCPS2, Article 3.3). Due to the new risks inherent to travel and contact during the pandemic, new risks associated with these aspects of participation must be addressed with the participants. To restart research, researchers must use the REB's **consent form addendum** (for previously approved studies) or **new consent form** (for new studies) to communicate the new risks related to research conduct during the pandemic (and until such time as the pandemic has been declared to have ended). The consent addendum and consent form template can be found in the Resource section of the REB website.

Section 3: New Risks Related to COVID-19

The considerations for "minimal risk" research involving in-person contact have changed; therefore, consent forms (for new studies) or consent addendums (for previously approved studies) must include any foreseeable risks related to research conduct during a pandemic. Researchers must ask the following critical questions prior to initiating in-person research to guide risk identification and mitigation strategies:

1. Where and with whom the research will be conducted?
2. What are the risks of transmission of COVID-19 to study participants and researchers?
3. How can research methods be modified to reduce the risk?

Examples of emerging ethical issues and risks are described below which **must be communicated to study participants during the consent or re-consent process and described in the REB application (for new studies) or change request application (for ongoing approved studies).**

Due to the dynamic nature of this pandemic, the REB may update these risks at any time. The onus is on the researcher to visit the REB website regularly or contact the REB at researchethics@ontariotechu.ca for new changes.

Risks related to in-person research

- Contact intensity: Increased in-person interactions with others (e.g. participant and researcher). What are the number of contacts that will occur in the activity setting (e.g. how many people will be present in one setting at the same time?)
- Location of research: Is the research taking place at multiple sites (e.g. on-campus, external sites such hospitals or private facilities, field research)? Is there a risk for researchers carrying the virus from one site to the next? Each region has a staggered approach when entering different restart phases; therefore, what is the status of COVID-19 at the location of the research? What public health directives are in place?
- Duration of study participation: What are the risks involved with the length of time spent on site as the risk increases with possible exposure to other individuals?
- Exposure during travel: Transportation considerations to the research site are important as public transportation can be a riskier activity vs walking or biking.
- Risks to 3rd parties: Risk of exposure means that there are new added risks of participants engaging in a study and coming home to others who may have elevated exposure risks. Is there a new risk to a participant if they are living with seniors, immunocompromised, children, those with increased susceptibility to contracting the virus?

It is important to note that:

- **Risks can be aggravated if proper sanitization procedures are not properly followed.**
- **Researchers must ensure that student researchers are supervised when conducting in-person data collection procedures.**

Increased vulnerability

- Physical and physiological – Some individuals are at greater risk of morbidity and mortality from the infectious disease (e.g. age, other underlying disease, immune system status).
- Psychological or emotional – Some individuals may experience an exacerbation of mental health issues because of the pandemic if they are asked to leave their home and interact with others (e.g. OCD, anxiety or depression).

Privacy and confidentiality

Participants must undergo screening for COVID-19 symptoms prior to conducting in-person research activities and personal information will be collected for contact tracing purpose if the need arises. As a result, new issues arise with respect to privacy and confidentiality which include:

- Collecting personal health information (PHI) when conducting active screening for on-campus activities.
- Collecting contact information for contact tracing.
- Impact to participants if the researchers are required to provide the Regional Public Health Department with participant names due to an infection on-campus or during study participation. What are the potential social, legal risks for that information?
- Interviews and focus groups: Impact of privacy when discussions are held 2 meters away from each other.
- Research anonymity and confidentiality cannot be guaranteed.
- Data management plan for the collection of PHI.

Section 4: Risk Mitigation

TCPS2, Chapter 2 (Balancing Risks and Potential Benefits) states "In research involving communities, risks and benefits must be considered from the perspective of the participant, the community and the individual members of the community (who may or may not be research participants)."

Researchers must adjust the research to lower the risk or postpone until the pandemic is over, or until there are new safety measures in place. **Researchers must include COVID-19 protocols and Standard Operating Procedures (SOP) that specifically address participant safety issues.** The REB shall make decisions based on the **risk-benefit ratio** presented in the researcher's application.

Researchers must ensure that risk mitigation strategies approved by the University are included in the research design such as:

- ✓ continuing to use secure, remote interactions/methods where feasible,
- ✓ use of non-medical masks or face covering for all participants,
- ✓ screening participants prior to conducting research procedures,
- ✓ informing participants in advance of all pertinent information with respect to arriving at the study location, including entry and exit points, waiting areas and timing of arrival, masks and glove requirements for the participant while at the study site, social distancing rules in effect, signage.
- ✓ ensuring the availability of sanitized washrooms for participants to use when on site,
- ✓ describing the use/provision of Personal Protective Equipment (e.g. masks, gloves) and proper disposal once used,
- ✓ describing the use/provision of hand sanitizer,
- ✓ prioritizing single use research apparatus where possible,
- ✓ incorporating physical distancing measures,
- ✓ describing sanitization procedures for any surfaces that participants may touch/interact with,
- ✓ detailing unanticipated problem reporting protocols if COVID-19 symptoms develop with study participants. The reporting procedure must follow REB SOP 207 (Ongoing Review of Approved Research).

Section 5: Requirements for REB application or Change Request Form

The status of your study will determine the type of application to submit to the REB. For new studies, use the REB's "Application for Ethical Review (v0.4)" found in the IRIS Research Portal. For studies that received REB approval but are on hold due to the pandemic, use the REB's "REB Change Request" form that is also found in the IRIS Research Portal.

New Studies	
Documents	**Requirements**
REB application (Application for Ethical Review v0.4) in IRIS	• Must include new ethical concerns outlined in section 3 of the document (e.g. risk related to in person research, increased vulnerability, and privacy and confidentiality considerations). Itemization of all risks and benefits related to in-person research during a pandemic.

New Studies	
Documents	**Requirements**
	• Detailed description of recruitment and consent plan. • Data management and participant data protection must indicate that anonymity and confidentiality cannot be guaranteed due to the requirement for contact tracing. • Data management plan for the collection of personal health information (PHI) related to screening. Note that collection of PHI should be minimized to only that which is necessary for screening or for the study itself. • Describe the unanticipated problem reporting protocol which will be used if COVID-19 symptoms develop in study participants. Refer to REB SOP 207 (Ongoing Review of Approved Research).
Consent Form	• Ontario Tech's consent form template must be used. • All attributable risks and benefits related to study participant and conducting research during a pandemic. See section 6 of the guidance document for wording. • Risk mitigation strategies outlined in section 4.
COVID-19 Standard Operating Procedure (SOP)/protocol	• Include a COVID-19 safety protocol/SOP as an appendix that is **participant-oriented**. This can be the same protocol/SOP submitted to the Faculty On-Campus Research Committee (FORC). • For research conducted off-site, research must adhere to the policies of those sites. Supporting documentation must be included as an appendix.

Studies on hold due to COVID-19	
Documents	**Requirements**
Change Request application in IRIS	• Must include new ethical concerns outlined in section 3 of the document (e.g. risk related to in person research, increased vulnerability, and privacy and confidentiality considerations). Itemization of all risks and benefits related to in-person research during a pandemic. • Update recruitment and consent plan.

	• Update data management and participant data protection to indicate that anonymity and confidentiality cannot be guaranteed due to the requirement for contact tracing. • Update data management plan for the collection of personal health information (PHI) related to screening. Note that collection of PHI should be minimized to only that which is necessary for screening or for the study itself. • Describe the unanticipated problem reporting protocol which will be used if COVID-19 symptoms develop in study participants. Refer to REB SOP 207 (Ongoing Review of Approved Research).
Consent Form Addendum	• If participants have consented to the study using a consent form that does not include COVID-19 related risks, they must be re-consented with the updated information using the REB's consent form addendum template. • All attributable risks and benefits related to study participant and conducting research during a pandemic. See section 6 of the guidance document for wording. • Risk mitigation strategies outlined in section 4. • Describe any modifications to the study procedures as a result of the COVID-19 pandemic.
COVID-19 Standard Operating Procedure (SOP)/protocol	• Include a COVID-19 safety protocol/SOP as an appendix that is **participant-oriented**. This can be the same protocol/SOP submitted to the Faculty On-Campus Research Committee (FORC). • For research conducted off-site, research must adhere to the policies of those sites. Supporting documentation must be included as an appendix.

Section 6: Risk Communication in Consent Forms

The following are examples of text that are now **required i**n consent forms in order to communicate the new risks and protocols:

"If you feel that you are in a vulnerable group with respect to COVID-19 effects (e.g. senior, immunocompromised, living with individuals that may be susceptible to COVID-19), it may be best that you do not participate in the study."

"Because you are coming on campus, the following safety protocols must be followed:

- ✓ Screening,
- ✓ Use of non-medical masks or face covering while participating in the research study,
- ✓ Follow instructions provided to you with respect to arriving at the study location, including entry points, designated waiting areas and washrooms, timing of arrival,
- ✓ Hand washing,
- ✓ Precautions taking public transit or travelling to the research site,
- ✓ Physical distance (maintaining 2-meter distance from others),
- ✓ Personal Protective Equipment (PPE) provided to participants by research team"

"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 in coming to the research site. As a result, we cannot guarantee privacy and confidentiality of your participation in the study."

"We cannot guarantee anonymity, as the personal contact information does identify you as a participant".

"Contact information will be kept separate from data collection through the research study to allow for de-identification of the research data (If applicable, as detailed in the protocol)."

For participation on campus: "During this time, the university may request information relating to all people entering and exiting our campus. As such please be advised that it may not be possible to keep your participation in a study confidential; however, no information about the data you share with us in the study will be shared outside of the research team."

"You maintain your right to withdraw from the study, including research data (if applicable). If you do withdraw, we will continue to maintain your contact information and will only give it Durham Public Health and the University if required for contact tracing."

"There may be additional risks to participating in this research during the COVID-19 pandemic that are currently unforeseen and, therefore, not listed in this consent form."

"If you think you have COVID-19 symptoms or have been in close contact with someone who has it, use the Government of Ontario's COVID-19 self-assessment tool and follow the instructions it provides to seek further care. In addition, you must inform the Principal Investigator **immediately** for follow up."

Section 7: Important Considerations

- To facilitate with REB submissions, researchers should seek REB consultation to restart research early. Please contact the REB at researchethics@ontariotechu.ca to book your consultation.
- **Peak submission periods are from July to November each year** where the review turnaround times are **extended** for the initial decision letter due to the high volume of submissions. The REB encourages researchers to submit their applications early, or if possible, during non-peak periods to minimize unforeseen delays.
- The considerations for "minimal risk" research involving in-person contact have changed, **conducting in-person research is considered above minimal risk**. Therefore, REB submissions involving in-person contact during the pandemic will be **reviewed at the REB's monthly REB meeting**. Researchers must aim to submit complete applications **2 weeks prior to meeting date for review**. The meeting dates are found on the REB's homepage.
- Refer to the REB's resources on the website for new ethical considerations.
- REBs are **independent in their decision making** and are accountable to the highest body that established them for the process of research ethics review (TCPS2, Article 6.2). Therefore, the decision-making of the REB is independent of any University committee/Task Force involved in re-starting in-person or on-campus research activities.
- **Reconsideration or appeals requests** to any REB decisions will follow **REB SOP 212: Process for Reconsideration or Appeal of Decisions of the REB**.