LAURENTIAN UNIVERSITY RESEARCH ETHICS BOARD (LUREB)
COVID-19 FREQUENTLY ASKED QUESTIONS

Approval of all research involving human participants is conditional on ongoing researcher compliance with all COVID-19 related government and public health restrictions. Currently, Laurentian University has implemented a plan for staged resumption of research activities and a *Request for Resumption of Research* procedure has been created. Researchers should consult the Laurentian University *Research Resumption Guidelines for Phased-In Face-to-Face Research with Human Participants* for the relevant application steps including the completion of a Risk Mitigation Plan (RMP). Researchers should note that the LUREB does not "manage" this process, nor does it replace the existing LUREB processes. Once the process is completed, the researcher may apply for LUREB review and approval. The LUREB may also impose additional conditions or suspend its approval according to evolving circumstances.

Are undergraduate student research projects being considered for ethics approval right now?

Yes. If there is a Departmental Research Ethics Committee, undergraduate research proposals will be submitted to this committee. If the Departmental committee determines that there is more than minimal risk, the proposal should be submitted to the REB within the ROMEO system. All the LU "Research Resumption Guidelines" must be followed.

Are any types of human participant research projects on hold during COVID-19?

Yes. Please consult the Laurentian University "Research Resumption Guidelines for Phased-In Face-to-Face Research with Human Participants" for more information.

What Phase of the Research Resumption Plan are we in? Is there a timeline for resumption of face-to-face research?

Laurentian University is currently in Phase 2 of the Research Resumption Guidelines which allows researchers to submit requests to resume face-to-face research with human participants. Three Categories of research (1. Virtual participation; 2. Research activity respecting 2-metre physical distancing; 3. research activity where 2-metre physical distancing is not possible) are listed in the *Research Resumption Guidelines for Phased-In Face-to-Face Research with Human Participants*. The REB will consider applications for research that fall under all three Categories provided that a *Request for Resumption of Research* has been completed and approved, sufficient justification is provided for the necessity of the research, and the benefits of the study outweigh the potential risks (including the risks of contracting and propagating COVID-19 as well as the social and psychological risks associated with participating in research during the pandemic). The REB will also consider the most current public health recommendations when conducting risk/benefit assessments.

The REB strongly encourages research activities that fall under Category 1 (virtual participation). If in-person research activities respecting 2-metre physical distancing (Category 2) or research activities where 2-metre physical distancing is not possible (Category 3) are anticipated, researchers should provide a justification as to why it would not be possible to modify the research activity to permit virtual participation or to respect physical distancing. Researchers must also describe how the benefits of the research outweigh the risks.

A working committee of the Vice-President Research, the Manager of Health & Safety, the REB Chair and REB Vice-Chair, are monitoring the situation regularly and based on the most current information from Public Health, Sudbury & District (PHSD). Changes in the *Research Resumption Guidelines for Phased-In Face-to-Face Research with Human Participants* will be communicated broadly to the university community through the office of the VP Research.

I have research in progress. Do I need to resubmit my ethics application?

If your original research design involved virtual interactions (e.g. online Survey, phone or ZOOM interviews or analysis of secondary data) and was previously approved by the LUREB without conditions, there is no need to resubmit.

I have research in progress. Do I need an amendment to my research?

This will be determined by the nature of the research. If you modify your recruitment or participant interactions to methods for virtual interaction, an REB amendment is required. Modifications are submitted through ROMEO. No other processes are required.

I have research in progress. Do I still need to add a RMP?

All previously approved human participant research involving face-to face participant interactions should be considered under conditional suspension. If your research has been approved by the LUREB, but conditionally suspended, submission of an RMP, LU approvals and a modification request through ROMEO are required before your research may resume.

If you "self-suspended" your research under a current LUREB Approval and wish to resume under modified (virtual) methods, a modification request should be submitted in ROMEO. No other processes are required.

If you "self-suspended" your research under a current LUREB Approval and wish to resume with face-to-face participant interaction, the Safety and VP Research approval processes must be completed and a modification request should be submitted in ROMEO along with this completed documentation. For the steps involved, please consult the *Research Resumption Guidelines for Phased-In Face-to-Face Research with Human Participants.*

If I already have approval from Health and Safety and the VP Research do I need to submit my research proposal or changes to LUREB?

Yes. All research with human participants requires LUREB approval. All modifications to REB proposals require LUREB approval of the amendments.

All new research anticipating face-to-face interactions with human participants requires completion of the Health and Safety and VP Research approval processes. Submission of the proposal and this supporting documentation is to be submitted in ROMEO for LUREB review and approval.

What should I put in the RMP? How much detail is needed? Do I need to put this information into the Research Methods (5.5) section in Romeo as well? What about the section on assessing risk (7.3)?

For completion of the Research Management Plan, please consult the LU *Research Resumption Guidelines for Phased-In Face-to-Face Research with Human Participants.*

For a new proposal, all details of the research plan should be included in the ROMEO submission. The RMP and permissions should be included as attachments.

For previously approved human participant research, modifications that are detailed within a RMP do not also need to be incorporated into the REB application form with the modification request; however, the REB may ask for additional safety measures if these are not addressed within the institutional plan.

Modifications to research in progress (including those detailed in the RMP) should be reported in the Annual Report in ROMEO.

Can I still conduct interviews off-campus?

Laurentian University is currently in Phase 2 of the Research Resumption Guidelines which allows researchers to submit requests to resume face-to-face research with human participants. Three Categories of research (1. Virtual participation; 2. Research activity respecting 2-metre physical distancing; 3. Research activity where 2-metre physical

distancing is not possible) are listed in the *Research Resumption Guidelines for Phased-In Face-to-Face Research with Human Participants*. The REB will consider applications for research that fall under all three Categories provided that a *Request for Resumption of Research* has been completed and approved, sufficient justification is provided for the necessity of the research, and the benefits of the study outweigh the potential risks.

If a researcher is working with a community agency, the agency or community requirements must also be met in the safety of the research design. Please consider the section below on "Vulnerability of human participants in the context of COVID-19."

The organization/community gave me permission to come on-site. Do I still need a RMP for LU?

Yes. The *Laurentian University Research Resumption Guidelines for Phased-In Face-to-face Research with Human Participants* requires the completion of an RMP for field (community-based) research. The organization/community permission is an additional approval to be included in your new LUREB submission or your modification request.

What if I have COVID-19 related research that is time sensitive and requires REB approval?

Please consult the LU "Research Resumption Guidelines." Both these and normal REB review and approval processes must be followed. The REB Chair will attempt to expedite extremely time-sensitive proposals, however, there may be greater risk factors to be considered that will require expert review.

Are there any other ethical issues I should consider due to COVID-19?

Yes. Protecting both researchers and research participants during the pandemic may require a complete rethinking of research design and methods, including the following aspects:

- Recruitment
- Incentives
- Written consent
- Interviews and focus groups online
- Privacy and security of online IT communication platforms and data security

What sort of risk mitigation strategies should I be considering in my research design or modification?

Researchers should consider risk mitigation strategies such as:

- Continuing to use secure, remote interactions/methods where feasible
- Re-confirm that the community agrees to this research moving forward during this time
- Ensure advance arrangements for appropriate spaces to hold meetings, and to ensure cleaning protocols are in place
- Screening research team members and participants as they arrive. Requiring research team members and participants to inform the main researcher contact if they develop symptoms
- Use/provision of PPE (masks, gloves)
- Use/provision of hand sanitizer
- Single use research apparatus where possible
- Physical distancing measures

If I change my research design in response to COVID-19, do I have to re-Consent participants?

TCPS (2018), Article 3.3 states that consent shall be an ongoing process. 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, may be pertinent to their decision to continue research participation, or may be relevant to the particular circumstances of individual participants. In particular, researchers shall disclose changes

to the risks or potential benefits of the research. This gives participants the opportunity to reconsider the basis for their consent in light of the new information.

Consent forms may need to be amended to include acknowledgement of the remote possibility that a participant could come into contact with someone with COVID-19 during their research pathway and to allow for contact tracing.

Are there sample paragraphs addressing COVID-19 considerations that could be included in my Consent forms?

"There is a remote possibility that during your research activities you could come into contact with someone with COVID-19. If this highly unlikely event were to occur, we are required by the Public Health Unit to retain on file your email address or phone number to share with them for contact tracing purposes"

"We have changed our procedures in this study because of the need to keep participants and researchers safe during the pandemic. We are now asking your consent to [describe change in procedure]. Risks associated with this include [describe risks]. Measures undertaken to reduce this risk include [describe risk mitigation]. All other aspects of the study described in the original consent remain the same."

Vulnerability of human participants in the context of COVID-19

Adapted from University of Toronto "Guidance for the Recovery of Human Research During the COVID-19 Pandemic" https://research.utoronto.ca/covid-19-research-innovation-updates/u-t-guidance-recovery-human-research-during-covid-19-pandemic

REBs and researchers should be aware that individuals, prospective participants, researchers, and institutions may not normally be considered vulnerable, but may become so by the very nature of public emergencies. Those already vulnerable may become acutely so (Article 4.7). The increased public risks and devastation that cause public emergencies to be declared can threaten autonomy and physical, emotional, institutional and social welfare or safety. They also bring inherent tensions and pressures that may impact deliberative decision making. Taking all of this into consideration, REBs and researchers should ensure that the risks and potential benefits posed by any proposed research are appropriately evaluated, including provisions for greater than normal attention to risk, where applicable." TCPS, Article 6.23

It is essential that researchers understand that the COVID-19 public emergency raises the baseline of vulnerability for all people. However, for some individuals and communities, ongoing and new circumstances may exacerbate vulnerabilities even further. Researchers should assess the vulnerability of both participants and research team members in terms of the following factors:

- Physical/physiological – attributes that put individuals at greater risk of morbidity and/or mortality from the disease (e.g., age, other diseases, immune system status)
- Psychological/emotional – attributes that may exacerbate mental health issues (e.g., obsessive-compulsive disorder, anxiety, depression) because of the pandemic, including pandemic directives and preventative measures (e.g., isolation, subjective fears)
- Social – attributes that put individuals at greater risk of exposure, of 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, dependants)

A combination of these factors may contribute to a participant's circumstances. Researchers should consider the highest level of vulnerability for their participant group when completing or amending their ethics protocol, obtaining informed consent and conducting the research.

It is important to consider that when researchers ask volunteers, who may not benefit from the research, to participate in face-to-face research, the volunteers are not only taking additional risks during the encounter, but also during the act of travelling to the location or meeting the researchers at a specific location.

Certain individuals or groups are at greater risk of getting an infection and developing severe complications from COVID-19 and these populations must be supported and protected during this time. Vulnerable individuals/groups may include, but are not limited to:

- Individuals over the age of 65 or children under the age of 16

- Individuals with pre-existing medical conditions (e.g. immunocompromised, diabetes, heart or lung disease)
- Individuals experiencing socio-economic challenges, such as inadequate or overcrowded housing
- Indigenous communities who may suffer disproportionately due to systemic inequalities

Face-to-face research involving vulnerable populations will require added considerations and measures for safety and, in some instances, participation in the research may not be advisable. The risk-to-benefit ratio may be too high in some cases to conduct the research in the manner proposed. Researchers may need to adjust the research to mitigate risk or continue to postpone until the health and safety conditions permit.

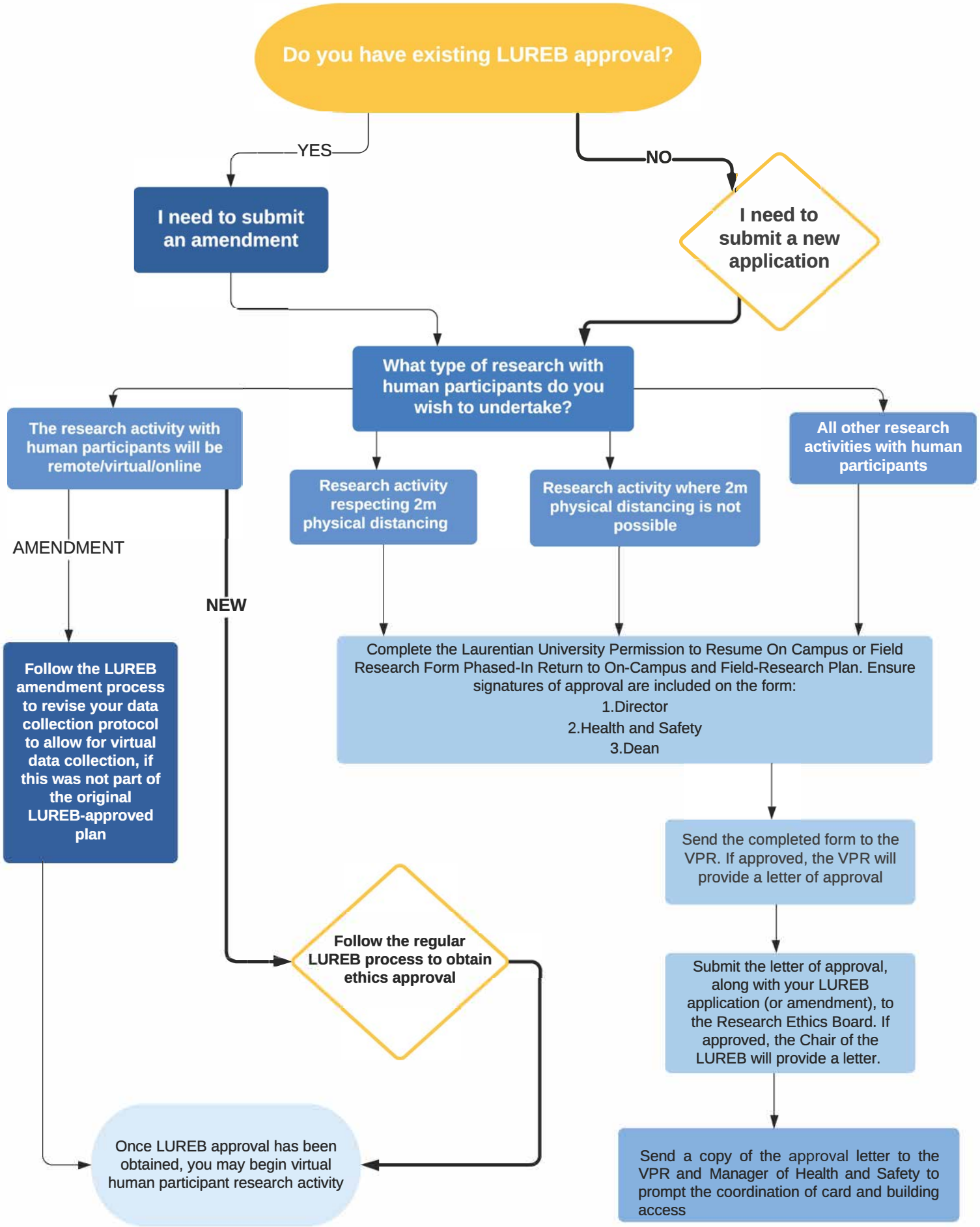
For any questions regarding Human Participant research, please contact ethics@laurentian.ca for guidance.

Appendix A

COVID-19 Risk Assessment According to Research Method

COVID-19 Research Risk	Research Method	Examples	Direct Contact
Level 0	Remote/virtual (not face to face)	Telephone interviews, online software interviews, mail-based surveys, Internet based surveys	None
Level 1	Interaction/observation	In-person Interviews, focus groups, surveys, computer-administered games	None or minimal physical distancing with PPE (masks) can be maintained
Level 2	Intervention	Introducing exercise regime; drug or natural health product testing (clinical trials)	Some physical contact (e.g., use of equipment to measure physical responses; saliva or blood collection)
Level 3	Physical treatment/ manipulation; indoor group activity	Physical therapy, dental procedure, biopsy	Sustained physical contact, close sustained interaction with others

Laurentian University
STEPS TO RESUME HUMAN PARTICIPANT RESEARCH



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