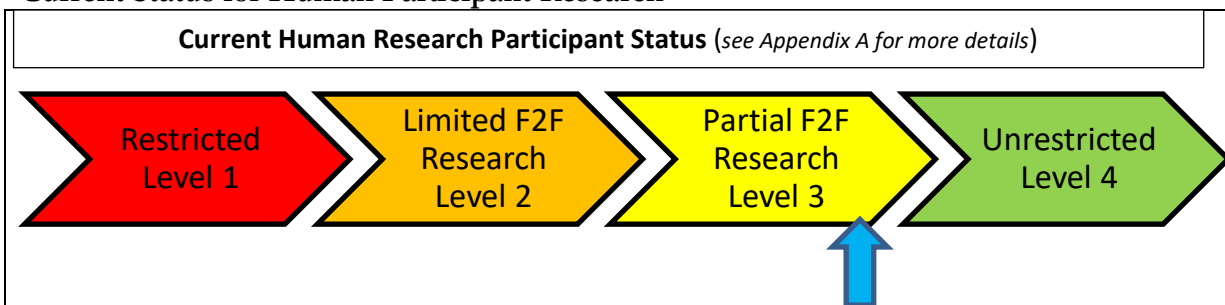


UREB Standard Operating Guidelines and Procedures

SOP #	REB.SOP.151
Title	Procedures for Phasing in Face-to-Face Human Participant Research during a Pandemic
Updated	July 14, 2021
Effective Date	September 24, 2020
Version	1.0
Prev. Version	N/A
Next Review	2025

\*This is a living document that will be revised as required by federal and provincial policy changes.

1. Current Status for Human Participant Research



*This status will be updated as situations change.*

2. Background

On March 17, 2020, the University, via the Research Office (RESO) and the University Research Ethics Board (UREB), requested that all research with human participants being conducted face-to-face (F2F) be immediately suspended due to the growing COVID-19 pandemic. Researchers were advised that the following operational procedures were effective immediately (and continue to be in place):

- The UREB will continue to accept and review new applications, modifications, renewals and study closures.
- In-person participant interactions (recruitment and data collection) must be replaced with telephone, online communications or other remote measures. If the cleared protocol involves any in-person participant interactions, researchers must complete a modification request as soon as possible (REB.FORM.002). The UREB will process modifications as quickly as possible.
- Researchers should be aware that any data collected in this pandemic environment may alter, skew or contaminate their results, unless their focus includes COVID 19 questions. Further, researchers may need to address/disclose this in publications and other knowledge dissemination activities when documenting method and timeframe of data collection.
- If researchers are able to postpone recruitment and data collection, we strongly recommend doing so. If this is a possibility, please let us know at [ethics@msvu.ca](mailto:ethics@msvu.ca) and we will place your file temporarily on hold. If you need to postpone data collection and have questions about extending your funding, please contact [research@msvu.ca](mailto:research@msvu.ca).
- If it is not possible to postpone the research or modify participant contact, please contact us as soon as possible at [ethics@msvu.ca](mailto:ethics@msvu.ca) with a formal request and full rationale. Requests will be considered on a case-by-case basis.

- Researchers with questions or concerns are encouraged to contact the Research Ethics Board via email at [ethics@msvu.ca](mailto:ethics@msvu.ca).
- As per the federal government advisory, research ethics applications directly addressing COVID-19, or pandemics generally, will be given first priority for ethics review.

Until further notice, and in keeping with Public Health guidelines, the UREB will continue adhere to the above-noted procedures. Notwithstanding UREB approval, any research conducted during the COVID-19 emergency must comply with federal and provincial public health advice, as well as COVID-related guidelines and requirements set forth by MSVU and the UREB (or other jurisdictions/facilities where the research will occur).

MSVU and the UREB have proposed a gradual and phased (see Appendix A) approach for resumption of research activity with human participants. Authorization to resume such face-to-face (F2F) human participant research activity will be granted through the request-review-approval process outlined in this document. The priority with F2F research shall remain focused on ensuring the health and safety of research participants, students, staff, and faculty, as well as the wider community. Clearance to proceed with F2F research will be granted in accordance with this document and directives from the Province of Nova Scotia. Only F2F research that has been approved through the process outlined herein can proceed at present.

On campus spaces will be inspected regularly and those that do not meet public health requirements or MSVU protocols and procedures will have access revoked immediately pending investigation by the MSVU Lab Access Committee. Violations may be considered a breach of responsible conduct of research, requiring additional investigation.

### 3. Principles and Guidelines

Decisions regarding resumption of face-to-face research activities will be guided by the following considerations:

- All research that can be conducted without F2F interaction should continue to do so; only research that cannot be conducted virtually will be considered during the application process.
- COVID-19 transmission risks must be part of the ethical considerations for the modification to, or approval of, any human participant research.
- Facilities Management's ability to serve buildings and ensure health and safety;
- Availability of a robust and viable pipeline for procuring required equipment and PPE for the research;
- Urgency of carrying out the research project because of timing issues (seasonal requirements, specific timelines for testing) or funding issues;
- On-campus research activities must adhere to all relevant Public Health directives from the Province of Nova Scotia's Chief Medical Officer of Health with respect to actions required to limit the spread of COVID-19. It is recommended that researchers review the [Nova Scotia Government's "COVID-19: Working"](#) website for information regarding keeping workplaces safe and guidance on items that may be helpful in developing the proposed plan.
  - Research activities must protect the physical, mental and emotional health and safety of MSVU students, staff, faculty, research participants and collaborators. Researchers – including students, and staff – must not feel compelled to work on campus during periods of restricted activities if they feel that it presents risks to their health and safety.
  - Every PI who makes an application to resume F2F research must be prepared for a sudden shut down following University or government directives or should other circumstances arise that would limit activities (e.g., a reported case of a COVID infection).
  - Every PI must take responsibility for not only adhering to safety protocols but must ensure that such protocols are adhered to by personnel under their supervision or guidance.
  - All PIs and personnel who are granted permission to pursue research have a duty of care for themselves and others to protect all from the transmission or exposure to the virus.

- Any situation that changes the circumstances surrounding the granting of permission must be reported in a timely manner by the PI for subsequent review by the MSVU Lab Access Committee/UREB.
- It must be noted that the same principles will apply to research that cannot be carried out remotely or at MSVU, but is carried out off campus as well as:
  - if the research is carried out in a third-party host organization, any additional constraints imposed by this host organization will also apply and,
  - such research may not allow for as much coordination as on-campus research, so that an abundance of caution must apply to these projects, including proper consideration of travel limitations and shared equipment use. As usual, before any research can be undertaken, it is also mandatory to ensure insurance coverage for all participants.
- Research that includes in-person participants faces specific challenges; the same principles as above should be applied to deciding whether it can be restarted. The first priority should be to move to online participation; if that is not possible, participation respecting the two-metre physical distancing should be considered; finally, if the latter is not possible, the implementation of physical barriers should be considered, including for instance Plexiglas dividers and wearing of appropriate personal protective equipment (PPEs).
- No research activity that can be carried out online will be approved for on-campus operation. If the research involves a combination of activities that must be conducted on campus and activities that can be conducted remotely (e.g. data analysis and other computer work), research personnel must not carry out the portion of research activities that can be performed remotely while they are on campus. Exceptionally, some limited on-campus data analysis work could be approved for cases when the experimental work process includes idle/waiting periods that are significantly shorter than a work shift.
- In addition to these principles and guidelines, priority focus for researcher access will be considered in order of relative importance for resumption of research activities on campus:
  - Research related directly to the COVID-19 pandemic;
  - Research for which data would be unduly difficult to replace or reproduce if the research activity is not able to be resumed as soon as can be allowed. This includes time-sensitive research continuity activities that cannot be paused for ongoing extended periods due to the potential of losing or disrupting sample protocols, data sequences, disruption of ongoing longitudinal studies, etc.;
  - Research that is directly related to a MSVU Post-Doctoral Fellow's research, or contribution to graduate student project completion, and in particular the research of those students who are close to graduation or for which delay, or disruption will cause high probability of incompleteness or personal hardship;
  - Research undertaken by a PI requiring a minimum of interaction with other individuals;
  - Research activity that cannot be adapted or carried out remotely and which involves external collaborators and/or funding; and
  - Research undertaken by disproportionately affected researchers in accordance with EDI principles.

**Note:** Research activities that do not fall into any of these priority areas will be considered collectively as the next equal-level priority.

#### 4. Procedures for Researchers

##### 4.1. Crisis Management Plan

Researchers must be prepared with a plan to handle possible COVID-19 cases as well as a plan to cease face-to-face research within a 24-hour period should conditions require. Please detail your plan and append it to the application.

##### 4.2. Risk Assessment

Researchers are asked to review this tool carefully to determine what level of risk is placed on the participants and/or research team. At this time, no high-risk research will be considered unless the

research is COVID-19 related. (Adopted from *Table 1- Tools to assess the risk level* in the [Government of Canada: Community-based measures to mitigate the spread of coronavirus disease \(COVID-19\) in Canada](#))

Please note that a space/safety audit will be required for any MSVU location used for research prior to submitting your application for resumption of F2F research on campus (See Section 5).

Risk level	Setting characteristics	Characteristics of individuals in the setting
<b>High</b>	<ul style="list-style-type: none"> <li>Individuals have interactions with many others in the setting</li> <li>Individuals have close contact (within 2 metres) with others</li> <li>Individuals have prolonged (i.e., &gt;15 minutes) interactions with others</li> <li>Individuals frequently have contact with potentially infectious high-touch surfaces (e.g., door handles, service counters, railings)</li> <li>The setting is a confined indoor space with no windows that can open</li> </ul>	<ul style="list-style-type: none"> <li>Most individuals are older adults or are known to have underlying medical or immune compromising conditions and are therefore at higher risk of severe illness</li> <li>Most individuals are considered essential workers and critical shortages in workforce or expertise could result if they contract COVID-19 at the setting</li> <li>Most individuals are visiting the setting from outside the community where it is located</li> <li>Few individuals are able to practice core personal practices</li> </ul>
<b>Medium</b>	<ul style="list-style-type: none"> <li>Individuals have/may have interactions with some others in the setting</li> <li>Individuals have/may have transient contact (within 2 metres for less than 15 minutes) with others when spending time in the setting</li> <li>Individuals have/may have contact with high-touch surfaces</li> <li>The setting is a confined indoor space, but has windows that can be opened</li> </ul>	<ul style="list-style-type: none"> <li>Some individuals may be older adults or are known to have underlying medical or immune compromising conditions and are therefore at higher risk of severe illness</li> <li>Some individuals are considered essential workers and critical shortages in workforce or expertise could result if they contract COVID-19 at the setting</li> <li>Some individuals are visiting the setting from outside the community where it is located</li> <li>Some individuals are able to practice core personal practices</li> </ul>
<b>Low</b>	<ul style="list-style-type: none"> <li>Individuals have few to no interactions with others in the setting</li> <li>Individuals are mostly able to avoid prolonged (i.e. &gt;15 minutes) close contact (within 2 metres) with others in the setting</li> <li>Contact with high-touch surfaces is infrequent</li> <li>The setting is not a confined indoor space, or is outdoors</li> </ul>	<ul style="list-style-type: none"> <li>Few individuals are older adults or are known to have underlying medical or immune compromising conditions and are therefore at higher risk of severe illness</li> <li>Few individuals are visiting the setting from outside the community where it is located</li> <li>Most individuals are able to practice core personal practices</li> </ul>
<p><b>Note:</b> There is currently insufficient evidence to define exposure risk by quantifying terms such as many vs. some vs. few, or frequently vs. sometimes vs. rarely.</p> <p>General principles for interpreting the risk level include:</p> <ul style="list-style-type: none"> <li>Settings with a higher number of contacts are presumed to have greater risk.</li> </ul>		

Risk level	Setting characteristics	Characteristics of individuals in the setting
		<ul style="list-style-type: none"> <li>Settings with close and prolonged contact with others are presumed to have greater risk.</li> <li>Settings with a higher frequency of contact with high-touch surfaces (i.e. surfaces frequently touched by others) are presumed to have greater risk.</li> <li>Settings with a higher proportion of individuals that are vulnerable to severe illness are presumed to have greater risk in terms of impact on the population.</li> <li>Settings with a higher proportion of individuals visiting from outside the community (i.e., from outside the city, town, county, or First Nations, Inuit or Métis community) are presumed to have greater risk in terms of introduction and geographic spread of the virus.</li> </ul>

### 4.3. Special Considerations

Researchers must take precautions when conducting research with vulnerable people and/or communities (e.g., Indigenous or remote communities; senior care facilities or homes; at-risk participants, etc.).

With the exception of COVID-19 research, **no research involving “high risk” individuals** are permitted. “High risk” individuals, as described by [Canada’s Public Health Agency](#), include those with certain medical conditions, weakened immune systems and older adults. Letters of Information must ask participants to identify if they are “high risk” and to seek medical advice if they are uncertain.

### 4.4. Participant Protection

#### 4.4.1. Researcher Self-Scan

All members of the research team who will be coming to campus or attending another site for research, whether participating in F2F research with participants or not, must do a daily self-scan for COVID-19. It is recommended that the research team utilize the COVID-19 Risk Assessment template (REB.TMPL.010)

- Any member of a research team who answers yes to any of these questions is prohibited from meeting in person with human participants or other research team members until a period of 14 days following the cessation of symptoms has elapsed or a negative COVID-19 test result has been obtained.

#### 4.4.2. Pre-scan of Participants (see Appendix B for a template)

Research that involves in-person participant contact requires a member of the research team to contact each study participant both prior to their visit(s) and upon arrival at the testing site. Specifically, researchers should utilize the **COVID-19 Risk Assessment template** (REB.TMPL.010)

If they respond with a yes to any of these questions, researchers are required to reschedule or cancel the study visit. Rescheduling should be after a period of 14 days following the cessation of symptoms has elapsed or a negative COVID-19 test result has been obtained.

#### 4.4.3. Cleaning Protocol for On-Campus Research

Ensure that you review the [Fall 2020 Operational Plan](#), and include in your application the cleaning protocol that will be used

- Off-Campus – Researchers must provide a cleaning protocol for the space(s) in which the research is taking place and append to the application package.

#### 4.4.4. Personal Protective Equipment (PPE)

Researchers must demonstrate that proper PPE for all research team members and participants is available and that all members of the research team have received training in the use of PPE.

## 5. Application Process

All researchers proposing to re-start face-to-face research are required to prepare a **Supplementary Research Form** (REB.FORM.018).

Prior to submitting the application package, researchers who are conducting research on campus are required to contact Steven Song ([steven.song@msvu.ca](mailto:steven.song@msvu.ca)) to schedule a space/safety audit of the proposed research space.

Applications must be submitted electronically to [ethics@msvu.ca](mailto:ethics@msvu.ca) and will be reviewed bi-weekly. Applications will be reviewed by the MSVU Lab Access Committee, which is comprised of: Associate Vice President, Research; Dean of Arts & Science; Director, Facilities Management; Safety Officer; Research Ethics Coordinator; Chair or Vice-Chair of the UREB. Additional members may be added as required (e.g., OHS, Human Resources, Risk Manager, University Research Ethics Board).

An assessment will be conducted, at a higher-level, of the impact of the proposed protocol on the overall level of activity and number of individuals in each location and across campus. This includes assessing the ability for the researchers to conduct their in-person research.

## 6. Forms and Documents to Use

- 6.1. REB.FORM.118 – COVID Supplementary Research Form
- 6.2. REB.FORM.002 – Modification Request
- 6.3. REB.TMPL.010 – COVID-19 Risk Assessment
- 6.4. REB.INFO.002 - Information Letter - COVID 19

## 7. Related Documents

### 7.1. Internal

- 7.1.1. REB.POL.001 – [University Research Ethics Policy](#)
- 7.1.2. REB.SOP.104 – [Emergency Preparedness](#)
- 7.1.3. [Fall 2020 Operational Plan](#)
- 7.1.4. MSVU SAFE App – <https://www.msvu.ca/campus-life/campus-services/safety-security-at-msvu/msvu-safe-app/>

### 7.2. External

- 7.2.1. *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS)*
- 7.2.2. Coronavirus disease (COVID-19): Prevention and Risks
- 7.2.3. Workers Compensation Board of Nova Scotia website for information regarding keeping workplaces safe, and guidance - <http://www.worksafeforlife.ca/COVID19> .
- 7.2.4. Nova Scotia 811 – When to Call About COVID-19 - <https://when-to-call-about-covid19.novascotia.ca/en>
- 7.2.5. NS Public Health directives are outlined at these websites:  
<https://novascotia.ca/coronavirus/>  
<https://novascotia.ca/coronavirus/working-during-covid-19/>

## 8. Acknowledgements

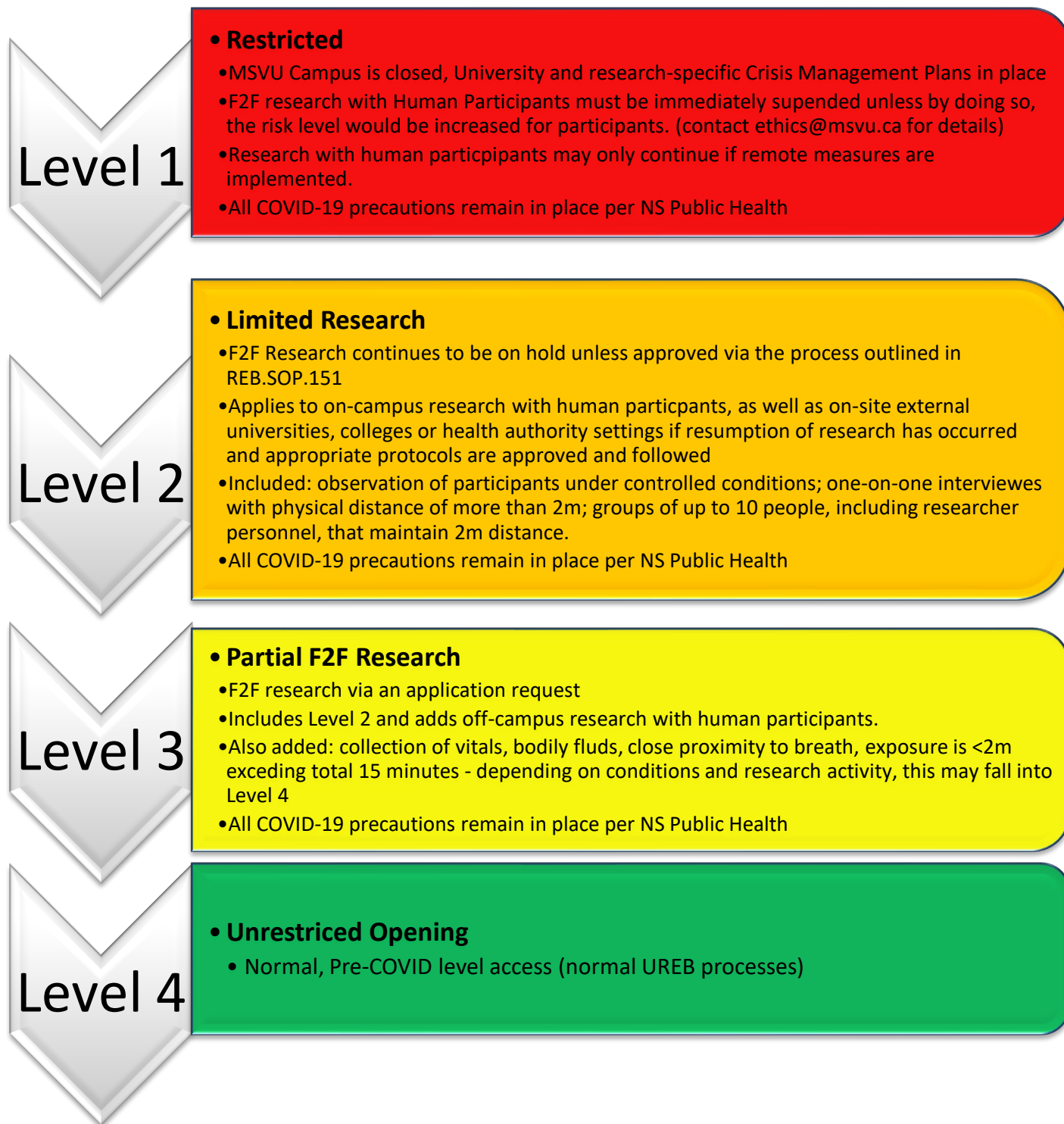
Mount Saint Vincent University wishes to acknowledge that this current iteration has been informed, in part, by documentation prepared by the following universities:

- Brock University - <https://brocku.ca/research-at-brock/office-of-research-services/research-ethics-office/> (July 2020)
- Dalhousie University - <https://www.dal.ca/dept/research-services/responsible-conduct-/research-ethics-.html> (June 2020)
- MacEwan University - <https://www.macewan.ca/wcm/OfficeofResearchServices/index.htm> (July 2020)
- McMaster University - <https://research.mcmaster.ca/mrebcovidfaqs/> (September 2020)
- Memorial University - [https://www.mun.ca/research/CRWGResActFrameworkREVISEDJUNE\\_24.pdf](https://www.mun.ca/research/CRWGResActFrameworkREVISEDJUNE_24.pdf) (June 2020)

- Nova Scotia Health Authority, COVID-19 Risk Assessment - [http://policy.nshealth.ca/Site\\_Published/covid19/document\\_render.aspx?documentRender.IdType=6&documentRender.GenericField=&documentRender.Id=78368](http://policy.nshealth.ca/Site_Published/covid19/document_render.aspx?documentRender.IdType=6&documentRender.GenericField=&documentRender.Id=78368) (August 2020)
- University of Alberta - <https://www.ualberta.ca/research/support/ethics-office> (June 2020)
- University of British Columbia - <https://ethics.research.ubc.ca/behavioural-research-ethics/ubc-behavioural-guidance-during-covid-19-research-restrictions> (July 2020)
- University of Lethbridge - <https://www.uleth.ca/research/covid-19-updates-researchers> (August 2020)

## Appendix A – Current Human Research Participant Status

NOTE: Please see [F2F-Research-Resumption](#) to see how MSVU Levels of F2F Research align with the Province of Nova Scotia's Reopening Plans





## Appendix B – Participant Risk Assessment Template

Please see REB.FORM.019 - [Forms and Applications \(msvu.ca\)](https://msvu.ca)

## Appendix C – Researcher Procedures for F2F Research

PLEASE SEE: [Researcher-Procedures-for-F2F-Research.pdf \(msvu.ca\)](#)