

Standard Operating Procedure

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| Document Number | REB.SOP.502 |
| Title | Resumption of Face-to-Face Human Participant Research During a Pandemic or Publicly Declared Emergency |
| Effective Date | April 28, 2023 |
| Next Review | Review as required (Situational) |
| Next Administrative Review | Review as required (Situational) |

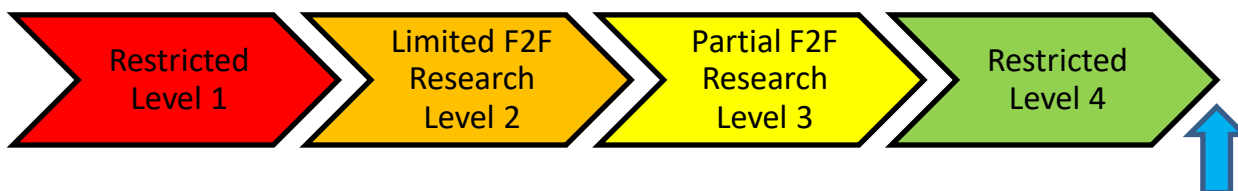
NOTE: This is a living document that will be revised as required by federal and provincial policy changes.

1. Current Status for Human Participant Research

April 28, 2023

Current Human Research Participant Status (see Appendix A for more details)

Level 4 - Unrestricted Opening - Normal Operations



This status will be updated as situations change.

2. Purpose

This standard operating procedure (SOP) describes the processes for the resumption of face-to-face (F2F) human participant research during a publicly declared emergency or pandemic.

3. Definitions

See the MSVU **REB Glossary of Terms (REB.INFO.001)**

4. Scope

This SOP pertains to the Organization, Research Ethics Boards (REB) and all researchers that involve human participants in research, in compliance with applicable policies and guidelines.

5. Responsibilities

All REB members, REB Office Personnel, Organizational Official(s) and Researchers are responsible for ensuring that the requirements of this SOP are met.

6. Situational Context

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 F2F be immediately suspended due to the growing COVID-19 pandemic. Since that time, several updates have been made to this document in alignment with Nova Scotia Public Health advice. On **March 21, 2022**, the Province of Nova Scotia removed the state of emergency and Public Health removed most of its mandates. Mount Saint Vincent University (MSVU) has authorized several restrictions to remain in place. Researchers are advised that the following operational procedures are effective immediately (and continue to be in place until at least June 24, 2022):

- In-person research requires additional clearance as outlined in this document, prior to the start of the research
- 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.
- Masking is required for all research teams and research participants while on the MSVU Campus.
- Researchers and participants are encouraged to continue to practice safe distancing where appropriate and if possible.
- For in-person research that takes place off-campus, researchers and participants must follow Public Health guidelines and/or the guidelines required at the location of the research.
- Room capacity limits will remain in place until June 24, 2022.
- More information on MSVU's Response to COVID-19 can be found here: [MSVU Response to COVID-19 – Mount Saint Vincent University](#)

Researchers with questions or concerns are encouraged to contact the Research Ethics Board via email at ethics@msvu.ca.

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).

Authorization to resume such 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.

7. Principles and Guidelines

Decisions regarding resumption of F2F 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;
- 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 pivot to remote measures following University or government directives or should other circumstances arise that would limit activities.
 - Every PI must take responsibility for not only adhering to safety protocols but must ensure that such protocols are adhered to by all 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).
- 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 Equity, Diversity, Inclusion and Accessibility (EDIA) principles.

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

8. Procedures for Researchers

8.1. Crisis Management Plan

Researchers must be prepared with a plan to handle possible COVID-19 cases as well as a plan to cease F2F research within a 24-hour period should conditions require. Please detail your plan and append it to the application.

8.2. Risk Mitigation

Researchers are asked to refer to the Government of Canada's website - [Individual and community-based measures to mitigate the spread of COVID-19 in Canada](#) to ensure that risks to participants and researchers are minimized. Please note that Table 1 on the website provides guidance on communicate-based measures to mitigate the spread of COVID-19. This tool should be reviewed 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.

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

8.3. Special Considerations

Researchers must take precautions when conducting research with people and/or communities at higher risk of contracting COVID-19 (e.g., Indigenous, or remote communities; senior care facilities or homes; at-risk participants, etc.).

8.4. Participant Protection

8.4.1. Research Team 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, should do a daily self-scan for COVID-19. It is recommended that the research team utilize the COVID-19 Risk Assessment template (REB.FORM.019)

- Please refer to the [Nova Scotia COVID-19 Guidance](#) for the most up to date information regarding isolation requirements.

8.4.2. Recommended Pre-scan of Participants (see REB.FORM.019)

Research that involves in-person participant contact may require 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.FORM.019). Please refer to the [Nova Scotia COVID-19 Guidance](#) for the most up to date information regarding isolation requirements.

8.4.3. 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.

9. Application Process

All researchers proposing to conduct F2F research are required to prepare a **Supplementary Research Form** (REB.FORM.018).

Applications must be submitted electronically to 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).

10. Forms and Documents to Use

All forms and Documents can be found at [COVID-19 Research Information - Mount Saint Vincent University \(msvu.ca\)](#)

- 10.1. REB.FORM.018 – COVID Supplementary Research Form
- 10.2. REB.FORM.002 – Modification Request
- 10.3. REB.FORM.019 – COVID-19 Risk Assessment
- 10.4. REB.TMPL.008 - Information Letter - COVID 19
- 10.5. REB.INFO.501 - F2F Research Resumption
- 10.6. REB.INFO.502 - Research Procedures for F2F Research

11. Related Documents

11.1. Internal

- 11.1.1. REB.POL.001 – [University Research Ethics Policy](#)
- 11.1.2. REB.SOP.501 – [Emergency Preparedness](#)
- 11.1.3. REB.INFO.501 – [F2F Research Resumption](#)
- 11.1.4. [REB.INFO.502 – Researcher Procedures for F2F](#)
- 11.1.5. MSVU's Response to COVID-19 - [MSVU Response to COVID-19 – Mount Saint Vincent University](#)
- 11.1.6. MSVU SAFE App – <https://www.msvu.ca/campus-life/campus-services/safety-security-at-msvu/msvu-safe-app/>

11.2. External

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

12. 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 (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 (October 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)

13. SOP History

| SOP Number | Key Changes | Effective Date |
|-------------|--|-------------------|
| REB.SOP.502 | Status Update - Effective May 1, 2023 MSVU moves to Unrestricted Opening (normal operations) | May 1, 2023 |
| REB.SOP.502 | Mask mandate changed to required | September 6, 2022 |
| REB.SOP.502 | Mask mandate changed to strongly recommended | June 27, 2022 |
| REB.SOP.502 | Dates updated; Mask requirement extended to June 24; deletion of sections that are no longer relevant or mandatory | June 1, 2022 |
| REB.SOP.502 | Status update; revisions to SOP; update to align with MSVU protocols; maintaining some restrictions (e.g., masks) and removal of visitor vaccine declaration | April 28, 2022 |
| REB.SOP.502 | Status update; revisions to SOP; update to align with Govt of Nova Scotia remove of PH mandates and MSVU maintaining some restrictions (e.g. masks) | March 21, 2022 |
| REB.SOP.502 | Status update; revisions to SOP; update to align with Govt of Nova Scotia updates | February 28, 2022 |
| REB.SOP.502 | Status update; revisions to SOP; update to align with Govt of Nova Scotia updates; | December 17, 2021 |
| REB.SOP.502 | Status update; revisions to SOP; update to risk mitigation to align with Govt of Canada Updates; | October 2021 |
| REB.SOP.502 | Status Updated. Minor revisions, inclusion of purpose, scope, definitions, responsibilities. Minor formatting changes. | July 16, 2021 |
| REB.SOP.502 | Status updated, SOP # changed to 502 Links to items in appendices to ensure up-to-date info | June 2021 |
| REB.SOP.151 | Original Version | September 2020 |

Appendix A – Current Human Research Participant Status

NOTE: Please see **REB.INFO.501 – Current Status of Resumption of F2F Research** to see how MSVU Levels of F2F Research align with the Province of Nova Scotia’s Reopening Plans

Level 1

- **Restricted**

- MSVU Campus is closed, University and research-specific Crisis Management Plans in place
- F2F research with Human Participants must be immediately suspended unless by doing so, the risk level would be increased for participants. (contact ethics@msvu.ca for details)
- Research with human participants may only continue if remote measures are implemented.
- All COVID-19 precautions remain in place per NS Public Health

Level 2

- **Limited Research**

- F2F Research continues to be on hold unless approved via the process outlined in REB.SOP.151
- Applies to on-campus research with human participants, as well as on-site external universities, colleges or health authority settings if resumption of research has occurred and appropriate protocols are approved and followed
- Included: observation of participants under controlled conditions; one-on-one interviewees with physical distance of more than 2m; groups of up to 10 people, including researcher personnel, that maintain 2m distance.
- All COVID-19 precautions remain in place per NS Public Health

Level 3

- **Level 3 Limited**

- F2F research via an application request
- Includes Level 2 and adds off-campus research with human participants.
- Also added: collection of vitals, bodily fluids, close proximity to breath, exposure is <2m exceeding total 15 minutes - depending on conditions and research activity, this may fall into Level 4
- Capacity Limits = 50%
- All COVID-19 precautions remain in place per NS Public Health

- **Level 3 Expanded**

- **same as Level 2 Limited, with the exception of: Capacity limits = 75%**

Level 4

- **Restricted Reopening**

- Some restrictions or additional mandates are required or strongly recommended - e.g., Masking, Room Capacity, Safe Distancing, etc.

- **OR**

- **Unrestricted Opening**

- Normal, Pre-COVID level access (normal UREB processes)

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