How to Submit to Resume Critical Human Participant SRC Activity: Process and Considerations

Considerations

Serious consideration needs to be given to the current public health emergency related to COVID-19 when contemplating a return to in-person human participant SRC activity.

Faculty members and supervisors are responsible for developing plans for the resumption of human participant SRC activity that demonstrate how risk is mitigated and ensure compliance with the federal guidelines on ethical conduct of research with human participants.

When feasible, modifications should be made to eliminate in-person interactions and conduct the SRC activity virtually.

REB amendments and other amendments to ongoing projects/studies should clearly outline all strategies being implemented to eliminate or reduce face-to-face interactions such as:

- Complete study visits via telephone or virtually.
- Employ contactless methods where possible.
- Conduct study activities at facilities where the participant will already be in attendance.
- Consider monitoring through the use of cameras to create additional physical separation.

Principal investigators (PIs) need to develop safety plans/standard operating procedures (SOPs) specific to their own activities before resuming/commencing research. SOPs should include operations, equipment, procedures, the type and location of the SRC activity, as well as the risk of exposure due to geographical location, facility types and other COVID-19 considerations.

The Safe Human Participant / Field SRC Plan Form can help to guide the development of these SOPs. Guidelines for general lab reopening should be included, as well as additional information such as:

- PPE modifications during the study. Outline procedures that may prevent safe physical distancing or require modified use of PPE. Document safety precautions and procedures that can be put in place to mitigate risk of infection for participants or research team members.
- Study population considerations. Can SRC activity aims/questions be addressed without recruiting those at greater risk of COVID-19 infection, recognizing that some studies/projects require working with these populations?

- Masks. What adjustments can be made to procedures and locations when study participants may not be able to wear masks? Consideration should be given to risk during interactions at the SRC activity space as well as the entire time that the participant will be on campus.
- Cleaning plan. A plan for cleaning and disinfecting spaces, including supplies such as PPE, cleaning supplies and waste management.

View the Principles and Guidance for the Limited Resumption of Critical Human Participant and/or Field SRC Activity document for more detail and examples.

Process to Request Approval for the Resumption of Human Participant SRC Activity

The process to request approval varies depending on the nature of the SRC activity. Ryerson Environmental Health and Safety (EHS) has developed a risk assessment template that can assist you in developing your safety plans.

Virtual or Online Human Participant SRC Activity

1. For studies that already have REB approval, please follow the REB amendment process to revise your data collection protocol to allow for virtual data collection, if this was not part of the original REB-approved plan.
2. Once REB approval has been obtained, you may begin virtual human participant SRC activity.

Human Participant SRC Activity Where 2-metre Physical Distancing Can Be Maintained

There are four levels of approval: (1) Chair/Director, (2) Dean (or designate), (3) REB, and (4) final approval by the Vice-President, Research and Innovation (VPRI). You will be notified of final approval by the Office of the Vice-President, Research and Innovation (OVPRI).

1. Complete the Safe Human Participant / Field SRC Plan Form and obtain Chair/Director approval. Once the Chair/Director gives their approval, they will send the Form to your Dean (or their designate) for approval. These approvals are conditional upon REB approval.
2. Once Chair and Dean approvals have been obtained, attach the Safe Human Participant / Field SRC Plan Form to your existing ethics protocol(s) and submit via the Online Ethics Portal for REB review and approval.
3. Faculty must also submit either a Request for Limited Return to On-Campus SRC Activity Google form if their human participant SRC activity is to take place on Ryerson's campus, or a Request for Limited Return to Off-Campus / Field SRC Activity Google form if their human participant SRC activity is to take place outside of Ryerson's campus*.

4. Once REB has approved the protocol, they will submit to VPRI for final approval.
5. You will be notified of final approval by the Office of the Vice-President, Research and Innovation (OVPRI).
6. Begin Human Participant SRC Activity following the safety plan and developed SOPs.

Human Participant SRC Activity Where 2-metre Physical Distancing Is Not Possible

There are five levels of approval: (1) Chair/Director, (2) Dean (or designate), (3) EHS, (4) REB, and (5) final approval by the VPRI. You will be notified of final approval by OVPRI.

1. Complete the Safe Human Participant / Field SRC Plan Form and obtain Chair/Director approval. Once the Chair/Director gives their approval, they will send the Form to your Dean (or their designate) for approval. These approvals are conditional upon Environmental Health and Safety (EHS) and REB approval.
2. Once Chair and Dean approvals have been received, they will send the Form to EHS. EHS will review it with a particular focus on the hierarchy of controls and safety protocols proposed.
3. Once EHS has approved it, they will return the Form to you. You should then attach the Safe Human Participant / Field SRC Plan Form to existing ethics protocol(s) and submit via the Online Ethics Portal for REB review and approval.
4. Faculty must also submit either a Request for Limited Return to On-Campus SRC Activity Google form if their human participant SRC activity is to take place on Ryerson's campus, or a Request for Limited Return to Off-Campus / Field SRC Activity Google form if their human participant SRC activity is to take place outside of Ryerson's campus*.
5. Once REB has approved the protocol, they will submit it to VPRI for final approval.
6. You will be notified of final approval by OVPRI.
7. Begin Human Participant SRC Activity following the safety plan and developed SOPs.

***** If travel is required for either of the above, you must complete the additional travel-related SOP sections on the Safe Human Participant / Field SRC Plan Form. Please refer to the Recommended Procedures for Safely Resuming Field SRC Activities (page 15) of the Principles and Guidance for the Limited Resumption of Critical Human Participant and/or Field SRC Activity document.

Note: If your human participant SRC activity is taking place at an off-campus location and is subject to that location's REB process, complete that REB process first and then follow the process outlined above. The review of your request will be expedited.