**Safe Research Plan (SRP) Template for studies involving vulnerable individuals**

This form is to be completed by the Principal Investigator (PI)/Lead Researcher to document their health and safety plans to support face-to-face research activities that involve vulnerable human participants. Research plans could minimize the number of people necessary to undertake the research safely. Where the research involves interaction with vulnerable human participants, additional procedures should be employed and are to be outlined below. This is an example plan and can be modified to describe research with specific requirements. Projects may include a range of research that could fall under different categories of mitigation needs. Please include details relevant to the main procedures that involve face-to-face human research, where there may be risk of COVID-19 exposure. Specifically, consider the population involved, proximity to participants, and duration of proximity, in addition to the nature of the research and the risks this may impose.

The purpose of the Safe Research Plan is to demonstrate to the REB that the necessary precautions and protocols are in place to protect research participants as well as the researcher(s). Guidelines are provided to assist in completing this plan. If a section is not applicable, indicate n/a.

|  |
| --- |
| **Introduction** |
| **Principal Investigator:**  | Click or tap here to enter text. |
| **Department/Faculty:** | Click or tap here to enter text. |
| **Contact Details:** | Click or tap here to enter text. |
| **Research Title:** | Click or tap here to enter text. |
| **Study Location:**  | Click or tap here to enter text. |
| **Study Setting:**  | Click or tap here to enter text. |
| **Proposed date for start of in-person contact with participants:**  | Click or tap to enter a date. |
| **REB # (if assigned)** | Click or tap here to enter text. |
| **Brief description of research activities:** | Click or tap here to enter text. |
| **Support by external funding agency:** | **If yes, provide details of funding:** Click or tap here to enter text. |

1. **Justification for In-Person Research**

*Describe why this research the study cannot proceed remotely and should be done in person.*

Click or tap here to enter text.

1. **Participants Description**

*Describe the risk profile of the research participant group (e.g., age, underlying medical conditions, etc.) and how risk will be managed for high risk members of the community in relation to the COVID-19.*

Click or tap here to enter text.

1. **Types of Gatherings (focus groups, interviews, meetings, presentations, etc.)**

*Describe what type of events are being considered, numbers of individuals to be involved in a specific setting and safety precautions for these. (this could include recruitment, interviews, focus groups, observation, questionnaires, physical testing etc.)*  Click or tap here to enter text.

1. **Community Based Research**

*Describe who has been involved in developing the Safe Research Plan.* Click or tap here to enter text.

1. **Research Involving Indigenous Communities**

*Indicate in your Safe Research Plan if your research involves Indigenous communities and describe who has been involved in developing the Safe Research Plan. Letters of agreement or support (MOUs, etc.) will need to be attached to your REB application before approval can be granted. You must confirm that the community has the capacity to accept to accept research activity and agrees to moving forward during this time.*Click or tap here to enter text.

1. **Travel and Accommodation***Does your project involve travel?* [ ]  **Yes** [ ]  **No**

*Describe how any required travel will be managed both for members of the research team and participants. Include information on COVID-19 measures that will be considered during travel and accommodation.* Click or tap here to enter text.

1. **Project Setting**
	1. In what physical space is the project taking place?
	 Click or tap here to enter text.
	2. Indicate if permissions or agreements will be required to conduct in-person research activities at the research site/organization?
	Click or tap here to enter text.
	3. Provide details on how many individuals (researchers + participants) will be in the same physical space at any given time.
	 Click or tap here to enter text.
	4. Does the physical space allow for physical distancing between individuals whenever possible in accordance with recommended guidelines. If no, provide details.
	Click or tap here to enter text.
	5. Indicate if there is adequate ventilation in the space.

[ ]  Yes

[ ]  No / Don’t know

[ ]  NA (outdoors)

1. **Transmission and PPE (for face-to-face interactions)**

*How will the risk of COVID-19 transmission be mitigated in your research setting?*

*Identify administrative and other controls (described here or above) as well as PPE being proposed to mitigate risk for each concern***.**

|  |
| --- |
| *If physical distance of two metres maintained what engineering/administrative controls implemented?* |
|  | Action | Comments/Description |
|[ ]  Entry/Exit process in place |  |
|[ ]  Reduced occupancy in room/space (maximum number of persons allowed in a facility to be used)  |  |
|[ ]  Cleaning protocols of space to be used |  |
|[ ]  Provision of hand washing stations |  |
|[ ]  Regular handwashing and/or sanitizing |  |
|[ ]  Equipment relocated where possible to support minimum physical distancing with participant |  |
|[ ]  Engineering controls have been implemented using change in location where possible, for example from indoors to outdoors. |  |
|[ ]  Consent forms (and other documents) are administered online.  |  |
| *List specific PPE required to mitigate risk during close proximity (<2 metres). Include consideration of duration and nature of planned interaction.* |
|[ ]  PPE has been sourced and will be available to researchers and participants, if required. |  |
|[ ]  Duration of interactions considerations |  |
|[ ]  Surface transmission considerations |  |

1. **Research Team member and Participant safety protocols**

|  |  |  |
| --- | --- | --- |
|  | Action | Comments/Description |
|[ ]  Awareness of research team members |  |
|[ ]  Self-assessment questions of participants and researchers |  |
|[ ]  Plan in the event that someone becomes sick or develops symptoms (return travel plans if required and self-management plans) |  |

1. **Does the nature of the research impose additional risk?** *Please explain and document what mitigation strategies are being implemented to reduce risk specific to those concerns*.
Click or tap here to enter text.
2. **Communications**

*Describe how your Safe Research Plan will be distributed to fellow researchers and participants. Are participants informed of the risks of COVID-19 during research? How will participants be informed of COVID-19 related safety measures that are being enforced?*Click or tap here to enter text.

1. **Consent Documents: COVID-19 considerations**

*Describe changes or additions for participant consent/re-consent in order to include details in relation to COVID-19.*

Click or tap here to enter text.

1. **Reporting**

*Describe how adherence to the Safe Research Plan will be ensured.*

* *How will changes to the plan be recorded?*
* *How will safety issues be reported?*
* *Who will be responsible for maintaining safe research protocols?*

Click or tap here to enter text.

**The PI confirms that:**

|  |
| --- |
|[ ]  Once approved, all personnel working with research participants review this form and will be given a copy |
|[ ]  Changes have been made to REB documents and COVID considerations added |
|[ ]  Changes/additions have been made to Consent of participants to include COVID specific details |
| [ ]   | I am responsible for ensuring that all necessary COVID-19 protocols are in place, including, but not limited to cleaning, screening and PPE requirements  |
| [ ]   | I will shut down the project in the event of any public health directive (e.g. tightening of restrictions related to pandemic status in the control of COVID-19). |
| [ ]   | I confirm that research protocols will continue to comply with the most up-to-date recommendations, directives and advisories about the spread of COVID-19 from government and public health officials and with those from institutions, organizations or funding agencies, relevant to the research project. |
| **PI Signature:**  |