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**SUMMARY PROTOCOL FORM (SPF)**

Office of Research – Research Ethics Unit – GM 900 – 514-848-2424 ext.  2425 – oor.ethics@concordia.ca – www.concordia.ca/offices/oor.html

**IMPORTANT INFORMATION FOR ALL RESEARCHERS**

Please take note of the following before completing this form:

* **You must not conduct research involving human participants until you have received your Certification of Ethical Acceptability for Research Involving Human Subjects (Certificate).**
* In order to obtain your Certificate, your study must receive approval from the appropriate committee:
	+ Faculty research and student research involving greater than minimal risk are reviewed by the University Human Research Ethics Committee (UHREC).
	+ Minimal risk student research is reviewed by the College of Ethics Reviewers (CER)
	+ Minimal risk student research conducted exclusively for pedagogical purposes is reviewed at the departmental level. **Do not use this form for such research.** Please use the Abbreviated Summary Protocol Form, available on the Office of Research (OOR) website referenced above, and consult with your academic department for review procedures.

Note that activities of this nature are considered to be a pedagogical exercise and not research meant to contribute to the body of knowledge of the field. As such, while results may be disseminated in the public domain, they cannot be published in peer reviewed journals or presented at conferences as research findings.

* Research funding will not be released until your Certificate has been issued, and any other required certification (e.g. biohazard, radiation safety) has been obtained. For information about your research funding, please consult:
	+ Faculty and staff: OOR
	+ Graduate students: School of Graduate Studies
	+ Undergraduate students: Financial Aid and Awards Office or the Faculty or Department
* Faculty members are required to submit studies for ethics approval by uploading this form, as well as all supporting documentation, to ConRAD. Access to ConRAD can be found in the MyConcordia portal.
* If necessary, faculty members may complete this form and submit it by e-mail to oor.ethics@concordia.ca along with all supporting documentation.
* Student researchers are asked to submit this form and all supporting documentation by e-mail, except for departmental review. Please note:
	+ Handwritten forms will not be accepted.
	+ Incomplete or omitted responses may result in delays.
	+ This form expands to accommodate your responses.
	+ Please ensure that all questions are answered completely (provide as much information as possible) and that samples of all materials are provided.
* Please allow the appropriate amount of time for your study to be reviewed:
	+ UHREC reviews greater than minimal risk research at the monthly meeting, which is usually scheduled on the second Thursday of each month. You must submit your study by the 1st of the month to be reviewed at that month’s meeting. Please confirm the date of the meeting on our webpage/FAQ section or with the staff of the Research Ethics Unit. Expedited reviews conducted by UHREC require a minimum of 8 weeks.
	+ CER reviews generally require 4 to 6 weeks.
* Research must comply with all applicable laws, regulations, and guidelines, including:
	+ The [*Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/)
	+ The policies and guidelines of the funding/award agency
	+ The [*Official Policies of Concordia University*](http://www.concordia.ca/about/policies/theme.html), including the *Policy for the Ethical Review of Research Involving Human Participants, VPRGS-3*.
* The Certificate is valid for one year. In order to maintain their approval and renew their Certificate, it is the researcher’s responsibility to submit an Annual Report Form one month before the expiry date that appears on the Certificate. Research must not be conducted under an expired certificate.
* Please note that all changes to an already approved protocol must be submitted for review and approved by the UHREC prior to being implemented. As such, you must submit an amendment request to the OOR.
* In order to ensure that ongoing research is compliant with current best practices and that the documents on file reflects the research activities researchers ate carrying out, complete resubmissions are required every 5 years.
* Please contact the Manager, Research Ethics at 514-848-2424 ext. 2425 if you need more information on the ethics review process or the ethical requirements that apply to your study.

**ADDITIONAL INFORMATION FOR STUDENT RESEARCHERS**

* If your research is part of your faculty supervisor’s research, as approved, please have him or her inform the Research Ethics Unit via e-mail that you will be working on the study.
* If your research is an addition to your faculty supervisor’s study, please have him or her submit an amendment request, and any revised documents via e-mail. You must not begin your research until the amendment has been approved.

**INSTRUCTIONS FOR COMPLETING THIS FORM**

* Please note that the SPF was designed to prompt reflection on the research project and all its possible implications. Please take the time to consider each question carefully in order to determine if and how it applies to your project.
* Please make sure that you are using the most recent version of the SPF by checking the OOR website.
* Please answer each question completely and provide as much information as possible; if you believe the question is not applicable, enter not applicable and provide justification.
* Do not alter the questions on this form or delete any material. Where questions are followed by a checklist, please answer by checking the applicable boxes.
* The form can be signed and submitted as follows:
	+ Faculty research submitted on ConRAD will be considered as signed as per section 16.
	+ SPFs for faculty research submitted via the faculty member’s official Concordia e-mail address will also be considered as signed as per section 16.
	+ Both faculty and student researchers may submit a scanned pdf of the signature page by e-mail. In this case, the full SPF should also be submitted by e-mail in Word or pdf format (not scanned).
	+ If you do not have access to a scanner, the signature page may be submitted on paper to the OOR.

**ADDITIONAL DOCUMENTS**

Please submit any additional documents as separate files in Word or PDF format.

**STUDY TITLE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

1. **BASIC INFORMATION**

**Principal Investigator’s Status:**

[ ]  Concordia faculty

[ ]  Concordia staff

[ ]  Visiting scholar

[ ]  Affiliate researcher

[ ]  Postdoctoral fellow

[ ]  PhD Student

[ ]  Master’s student

[ ]  Undergraduate student

[ ]  Other (please specify):

**Type of Submission:**

[ ]  New study

[ ]  Modification or a resubmission of an approved protocol. Approved study number (e.g. 30001234): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Where will the research be conducted?**

[ ]  Canada

[ ]  Another jurisdiction: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**2. STUDY TEAM AND CONTACT INFORMATION**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Role** | **Name** | **Department** | **Phone #** | **Email Address** |
| Principal Investigator |  |  |  |  |
| Faculty Supervisor (For student research only) |  |  |  |  |

**Additional Team Members**

**Please provide names of all team members that will be interacting with human participants or handling research data, as well as those authorized to correspond with the OOR on behalf of the PI**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Role** | **Name** | **Department /**  | **Phone #** | **e-mail address** |
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**Committee Members (For research conducted by PhD/Master students):**

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| --- | --- |
| **Committee Member** | **Department** |
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**Multi-Jurisdictional Research**

Does the research involve researchers affiliated with an institution other than Concordia? If so, please complete the following table, including the Concordia researcher’s role and description of the activities to be conducted at Concordia. If researchers have multiple institutional affiliations, please include a line for each institution.

*If applicable, please provide a copy of any additional submissions and ethics certification from the collaborating institutions.*

|  |  |  |  |
| --- | --- | --- | --- |
| **Researcher’sName** | **Institutional Affiliation** | **Role in the research (e.g. principal investigator, co-investigator, collaborator)** | **Research activities that will be conducted at this specific institution** |
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**3. PROJECT AND FUNDING SOURCES**

Please list all sources of funds that will be used for the research. Please note that fellowships or scholarships are not considered research funding for the purposes of this section.

|  |  |  |
| --- | --- | --- |
| **Funding Source** | **Project Title\*** | **Award Period**† |
| **Start** | **End** |
|  |  |  |  |
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Notes:

\* Please provide the project title as it appears on the Notice of Award or equivalent documentation.

† If you have applied for funding and the decision is still pending, please enter “applied”.

**4. OTHER CERTIFICATION REQUIREMENTS**

1. Will the research take place at the PERFORM Centre?

[ ]  Yes [ ]  No

1. Does the research involve any of the following (check all that apply):

 [ ]  Controlled goods or technology

 [ ]  Hazardous materials or explosives

 [ ]  Biohazardous materials

 [ ]  Human biological specimens

 [ ]  Radioisotopes, lasers, x-ray equipment or magnetic fields

 [ ]  Protected acts (requiring professional certification)

 [ ]  A medical intervention, healthcare intervention or invasive procedures

*Please submit any certification or authorization documents that may be relevant to ethics review for research involving human participants.*

**5. LAY SUMMARY**

Please provide a brief description of the research in everyday language. The summary should make sense to a person with no discipline-specific training and it should not use overly technical terms. Please describe the project and its objectives, including any research questions to be investigated. Please also include the anticipated value or benefits to society of the research. Finally, how will results be disseminated (e.g. thesis, presentations, internet, film, publications)?

Please do not submit the thesis proposal or grant application.

**6. RISK LEVEL AND SCHOLARLY REVIEW**

As part of the research, will participants be exposed to risk that is greater than minimal?

*Greater than minimal risk means that the probability and magnitude of possible harms and risks implied by participation in the research are greater than those encountered by participants in aspects of their everyday life that relate to the research.*

|  |
| --- |
|[ ]  Yes |
|[ ]  No |

Has this research received favorable review for scholarly merit?

*Scholarly review is not required for minimal risk research.*

*For faculty research, funding from a granting agency such as CIHR, FQRSC, or CINQ is considered evidence of such review. Please provide the name of the agency.*

*For student research, a successful defense of a thesis or dissertation proposal is considered evidence of such review. Please provide the date of your proposal defense.*

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| --- | --- | --- |
|[ ]  Yes | Funding agency or date of defense: | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|[ ]  No |  |
|[ ]  Not required |

If you answered no, please submit a Scholarly Review Form, available on the OOR website. For studies to be conducted at the PERFORM Centre, please submit the Scientific Review Evaluator Worksheet.

**7. RESEARCH PARTICIPANTS**

|  |
| --- |
| Will any of the participants be part of the following categories? *Please only check a box if the category of participant is a target population for this study.* |
|[ ]  Minors (individuals under 18 years old) |
|[ ]  Individuals with intellectual disabilities  |
|[ ]  Individuals with cognitive disabilities |
|[ ]  Members of Canada’s First Nations, Inuit, or Métis peoples |
|[ ]  Vulnerable individuals or groups(vulnerability may be caused by limited capacity, or limited access to social goods, such as rights, opportunities and power, and includes individuals or groups whose situation or circumstances make them vulnerable in the context of the research project, or those who live with relatively high levels of risk on a daily basis)  |

1. Please describe potential participants, including any inclusion or exclusion criteria.
2. Indicate if participants are a captive population (e.g. prisoners, residents in a center) or are in any kind of conflict of interest relationship with the researcher such as being students, clients, patients or family members. If so, explain how perceived coercion will be addressed in order to ensure that participants do not feel pressure to participate or perceive that they may be penalized for choosing not to participate.
3. Please describe in detail how potential participants will be identified, and invited to participate. In addition, please submit all recruitment materials to be used (e.g. poster(s), flyers, cards, advertisement(s), letter(s), telephone, email, and other verbal scripts).

*Note that while the snowball method of recruitment is acceptable, in order to protect the potential participants’ right to privacy and confidentiality, the researcher is not permitted to initiate direct contact with a potential participant whose contact information is not publicly available. Rather, recruitment material must be provided by the researcher to their contacts for further dissemination. Those interested would then contact the researcher directly.*

1. Please provide the anticipated start and end date of the research project.

*Note that recruitment or direct interaction for data gathering purposes with human participants is not permitted until full ethics approval is awarded. Conducting research without valid ethics approval is considered research misconduct. Only UHREC/CER approved versions of research documents can be used.*

1. Please provide a detailed, sequential description of the procedures to be used in this study. Describe all methods that will be used (e.g. fieldwork, surveys interviews, focus groups, standardized testing, video/audio taping), as well as the setting in which the research will take place. In addition, please submit all instruments to be used to gather data, for example questionnaires or interview guides for each type of participant.
2. Please describe any compensation participants may receive. Indicate the terms for receiving compensation, its value, and what happens to the compensation if a participant withdraws,
3. Do any of the research procedures require special training, such as medical procedures or conducting interviews on sensitive topics or with vulnerable populations? If so, please indicate who will conduct the procedures, what their qualifications are and whether they have previous experience.
4. When doing research with certain groups of participants (e.g. school children, cultural groups, institutionalized people) and/or in other jurisdictions, organizational /community/governmental permission is sometimes needed. If applicable, please explain how this will be obtained. Include copies of approval letters once obtained.

**8. INFORMED CONSENT**

*Please note that each participant should be provided with a copy of the consent form in addition to the one they sign, which is to be kept by the researcher.*

*Written consent forms and oral consent scripts should follow the consent form template available on the OOR website. Please include all of the information shown in the sample, adapting it as necessary for the research.*

1. Please explain in detail the process for soliciting informed consent from potential participants. In addition, please submit the written consent form.
2. Please note that written consent is the preferred method for obtaining consent. However, in certain circumstances, oral consent may be appropriate. If oral consent will be used, please submit a consent script and describe how consent will be documented.

*The use of an oral consent procedure needs to be justified and its approval is at the discretion of the applicable ethics committee (either the UHREC or CER). Note that convenience cannot be used as justification.*

1. Does the research involve individuals belonging to cultural traditions in which individualized consent may not be appropriate, or in which additional consent, such as group consent or consent from community leaders, may be required? If so, please describe the appropriate format of consent, and how it will be solicited.

**9. DECEPTION**

1. Does the research involve any form of deception of participants? If so, please describe the deception, explain why the deception is necessary, and explain how participants will be de-briefed at the end of their participation. If deception is involved, please submit a debriefing script.

*Please note that deception includes giving participants false information, withholding relevant information, and providing information designed to mislead.*

1. If deception is involved, please note that participants must be provided with the opportunity to refuse consent and request the withdrawal of their data once they know the details of the study. This should take place while it is still possible to give participants this option (e.g. prior to de-identification, publication, etc.). Please explain how this will be done and what timeline will be provided to participants for withdrawal of their data. Include a checkbox in the debriefing script so participants can clearly indicate their choice and a section for the participant’s signature. Please provide a copy of the debriefing script.

**10. PARTICIPANT WITHDRAWAL**

a) Please explain how participants will be informed that they are free to discontinue their participation at any time without negative consequences.

b) Please explain what will happen to the information obtained from a participant if he or she withdraws. For example, will their information be destroyed or excluded from analysis if the participant requests it? Please describe any limits on withdrawing a participant’s data, such as a deadline related to publishing data. Note that a clear deadline such as a specific date or timeframe must be provided.

**11. RISKS AND BENEFITS**

a) Please identify any foreseeable benefits to participants.

b) Please identify any foreseeable risks to participants, including any physical or psychological discomfort; emotional, social, legal, or political risks; risks to their relationships with others, or to their financial well-being. Please take the time to consider this question and mention any type of risk,

no matter how remote the likelihood of it occurring.

c) Please describe how the risks identified above will be minimized. For example, if individuals who are particularly susceptible to these risks will be excluded from participating, please describe how they will be identified. Furthermore, if there is a chance that researchers will discontinue participants’ involvement for their own well-being, please state the criteria that will be used.

d) Should the risks detailed above be realized, please describe how the situation will be managed. For example, if referrals to appropriate resources are available, please provide a list. If there is a chance that participants will need first aid or medical attention, please describe what arrangements have been made.

**12. REPORTABLE SITUATIONS AND INCIDENTAL FINDINGS**

1. Is there a chance that the research might reveal a situation that would have to be reported to appropriate authorities, such as child abuse or an imminent threat of serious harm to specific individuals? If so, please describe the situation, how it would be handled, and who the proper authorities are.

*Please note that legal requirements apply in such situations. It is the researcher’s responsibility to be familiar with the laws in force in the jurisdiction where the research is being conducted.*

1. Is there a chance that the research might reveal a material incidental finding? If so, please describe how it would be handled.

*Please note that a material incidental finding is an unanticipated discovery made in the course of research but that is outside the scope of the research, such as a previously undiagnosed medical or psychiatric condition that has significant welfare implications for the participant or others.*

**13. CONFIDENTIALITY, ACCESS, AND STORAGE**

1. Please describe the path of the data from collection to storage to its eventual archiving or disposal, including details on short and long-term storage (format, duration, and location), measures taken to prevent unauthorized access, who will have access, and final destination (including archiving, or destruction).
2. Please identify the access that the research team will have to participants’ identity:

*If you check more than one box, please specify the category of participants it applies to.*

|  |  |  |  |
| --- | --- | --- | --- |
|  | Category | Definition | Category of Participant |
|[ ]  Confidential | The research team will know the participants’ real identity, but it will not be disclosed. |  |
|[ ]  Participant Choice | Participants will be able to choose which level of disclosure they wish for their real identity. |  |
|[ ]  Disclosed | The research team will know the participants’ real identity, and it will be revealed in accordance with their consent. |  |
|[ ]  Anonymous | The information provided never had identifiers associated with it, and the risk of identification of individuals is low, or very low. |  |
|[ ]  Anonymous results, but identify who participated | The information provided never had identifiers associated with it. The research team knows participants’ identity, but it would be impossible to link the information provided to link the participant’s identity. |  |
|[ ]  Pseudonym | Information provided will be linked to an individual, but that individual will only provide a fictitious name. The research team will not know the real identity of the participant.  |  |
|[ ]  Coded | Direct identifiers will be removed and replaced with a code on the information provided. Only specific individuals have access to the code, meaning that they can re-identify the participant if necessary.  |  |
|[ ]  Indirectly identified | The information provided is not associated with direct identifiers (such as the participant’s name), but it is associated with information that can reasonably be expected to identify an individual through a combination of indirect identifiers (such as place of residence, or unique personal characteristics). |  |
|[ ]  Other (please describe) |  |  |

1. Would the revelation of participants’ identity be particularly sensitive, for example, because they belong to a stigmatized group? If so, please describe any special measures that will be taken to respect the wishes of the participants regarding the disclosure of their identity.
2. Please describe what access research participants will have to study results, and any additional information that will be provided to participants post-participation (e.g. resources, etc.).
3. In some research traditions, such as participatory action research, and research of a socio-political nature, there can be concerns about giving participant groups a “voice”. This is especially the case with groups that have been oppressed or whose views have been suppressed in their cultural location. If these concerns are relevant for the current participant groups, please describe how they will be addressed in the project.

*Please note that for the purpose of this evaluation, co-researchers in a participatory research action are considered participants and must consent to participate and provide oral or written consent.*

**14. ADDITIONAL ISSUES**

Bearing in mind the ethical guidelines of your academic or professional association, please comment on any other ethical concerns which may arise in the conduct of this research. For example, are there responsibilities to participants beyond the purposes of this study?

**15. DECLARATION AND SIGNATURE**

**Study Title:**

I hereby declare that this Summary Protocol Form accurately describes the research project or scholarly activity that I plan to conduct. I will submit a detailed modification request if I wish to make modifications to this research.

I agree to conduct all activities conducted in relation to the research described in this form in compliance with all applicable laws, regulations, and guidelines, including:

* + The [*Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/)
	+ The policies and guidelines of the funding/award agency
	+ The [*Official Policies of Concordia University*](http://www.concordia.ca/about/policies/theme.html), including the *Policy for the Ethical Review of Research Involving Human Participants, VPRGS-3*.

### Principal Investigator Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

### Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**FACULTY SUPERVISOR STATEMENT (REQUIRED FOR STUDENT PRINCIPAL INVESTIGATORS):**

I have read and approved this project. I affirm that it has received the appropriate academic approval, and that the student investigator is aware of the applicable policies and procedures governing the ethical conduct of human participant research at Concordia University. I agree to provide all necessary supervision to the student. I allow release of my nominative information as required by these policies and procedures in relation to this project.

### Faculty Supervisor Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

### Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_