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**SUMMARY PROTOCOL FORM (SPF)**

Office of Research – Research Ethics Unit – GM 900 – 514-848-2424 ext. 7481 – 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 is reviewed by the University Human Research Ethics Committee (UHREC).
	+ Minimal risk student research is reviewed by the College of Ethics Reviewers (CER; formerly the “Disciplinary College”), except as stated below.
	+ 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.
* 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 encouraged to submit studies for ethics by uploading this form, as well as all supporting documentation, to ConRAD, which 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 allow the appropriate amount of time for your study to be reviewed:
	+ UHREC reviews greater than minimal risk research when it meets on the second Thursday of each month. You must submit your study 10 days before the meeting where it is to be reviewed. You will normally receive a response within one week of the meeting. Please confirm the deadline and date of the meeting with the staff of the Research Ethics Unit.
	+ CER reviews, and delegated reviews conducted by UHREC generequire 2 to 4 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 your approval and renew your Certificate, please submit an Annual Report Form one month before the expiry date that appears on the Certificate. You must not conduct research under an expired Certificate.
* Please contact the Manager, Research Ethics at 514-848-2424 ext. 7481 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 make sure that you are using the most recent version of the SPF by checking the OOR website.
* Please answer each question on the form; if you believe the question is not applicable, enter not applicable.
* 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.

**1. BASIC INFORMATION**

**Study Title:**

**Principal Investigator:**

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| --- |
| **Principal Investigator’s Status:** |
|[ ]  Concordia faculty or staff |
|[ ]  Visiting scholar |
|[ ]  Affiliate researcher |
|[ ]  Postdoctoral fellow |
|[ ]  PhD Student |
|[ ]  Master’s student |
|[ ]  Undergraduate student  |
|[ ]  Other (please specify):  |

**Type of submission:**

|  |
| --- |
|[ ]  New study |
|[ ]  Modification or an update of an approved study. Approved study number (e.g. 30001234):  |

**Where will the research be conducted?**

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| --- |
|[ ]  Canada |
|[ ]  Another jurisdiction:  |

**2. STUDY TEAM AND CONTACT INFORMATION\***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Role** | **Name** | **Institution† / Department / Address**‡ | **Phone #** | **e-mail address** |
| Principal Investigator |  |  |  |  |
| Faculty supervisor§ |  |  |  |  |
| Committee member| |  |  |  |  |
| Committee member| |  |  |  |  |

|  |
| --- |
| Additional Team Members° |
|  |  |  |  |  |
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Notes:
\* If additional space is required, please submit a list of team members as a separate document.

†For team members who are external to Concordia only.

‡For individuals based at Concordia, please provide only the building and room number, e.g. GM-910.03.

§For student research only.

|For research conducted by PhD and Master’s students only.

°Please include all co-investigators and research assistants.

**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\*** | **Grant Number†** | **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**

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 do not submit your 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?

*Minimal risk means that the probability and magnitude of the risks are greater than those to which participants would be exposed in those aspects of their daily lives that are pertinent 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.*

|  |  |  |
| --- | --- | --- |
|[ ]  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? |
|[ ]  Minors (individuals under 18 years old) |
|[ ]  Individuals with diminished mental capacity |
|[ ]  Individuals with diminished physical capacity |
|[ ]  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. Please describe in detail how potential participants will be identified, and invited to participate. Please submit any recruitment materials to be used, for example, advertisements or letters to participants.
3. Please describe in detail what participants will be asked to do as part of the research, and any procedures they will be asked to undergo. Please submit any instruments to be used to gather data, for example questionnaires or interview guides.
4. 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 and what their qualifications are.

**8. INFORMED CONSENT**

1. Please explain how you will solicit informed consent from potential participants. Please submit your written consent form. In certain circumstances, oral consent may be appropriate. If you intend to use an oral consent procedure, please submit a consent script containing the same elements as the template, and describe how consent will be documented.

*Please note: 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 your research.*

1. Does your 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 you will solicit it.

**9. DECEPTION**

Does your 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 applicable, please submit a debriefing script.

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

**10. PARTICIPANT WITHDRAWAL**

a) Please explain how participants will be informed that they are free to discontinue at any time, and describe any limitations on this freedom that may result from the nature of the research.

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.

**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, and risks to their relationships with others, or to their financial well-being.

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) Please describe how you will manage the situation if the risks described above are realized. 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, and how it would be handled.

*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 your 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).

b) Please identify the access that the research team will have to participants’ identity:

|  |  |
| --- | --- |
|[ ]  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 indentifiers (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). |
|[ ]  Confidential | The research team will know the participants’ real identity, but it will not be disclosed. |
|[ ]  Disclosed | The research team will know the participants’ real identity, and it will be revealed in accordance with their consent. |
|[ ]  Participant Choice | Participants will be able to choose which level of disclosure they wish for their real identity. |
|[ ]  Other (please describe) |  |

1. Please describe what access research participants will have to study results, and any debriefing information that will be provided to participants post-participation.

d) 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 you will take to respect the wishes of your participants regarding the disclosure of their identity.

e) In some research traditions, such as 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 your participant group, please describe how you will address them in your project.

**14. MULTI-JURISDICTIONAL RESEARCH**

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

|  |  |  |  |
| --- | --- | --- | --- |
| **Researcher’sName** | **Institutional Affiliation** | **Role in the research (e.g. principal investigator, co-investigator, collaborator)** | **What research activities will be conducted at each institution?** |
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**15. 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?

**16. 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: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_