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**INSTRUCTIONS FOR PREPARING A CONSENT FORM**Office of Research – Research Ethics Unit – GM 900 – 514-848-2424 ext. 7481 – oor.ethics@concordia.ca – http://www.concordia.ca/research/for-researchers/ethics.html –

## HOW TO USE THIS DOCUMENT

This document gives Concordia researchers guidance on writing their consent forms, where such forms are required. It is not intended to replace existing substantive regulations or policies on informed consent.

This document explains how to complete the “Information and Consent Form Template” available on the Office of Research website listed above and on CSpace. For example, the Template has blanks that need to be filled in, as indicated by brackets “[ ]”; this document explains what information should be included. Similarly, not all statements in the Template are appropriate for all research; this document explains how to determine what to include. Please note that in the following pages, the text in italics represents instructions, whereas the plain text represents statements from the Template.

The Template may not be appropriate for all situations. For example, research involving minors generally requires parental consent, and there are special considerations for research in which consent is documented electronically. The Office of Research hopes to develop alternative templates in the coming months. In the meantime, please contact the Manager, Research Ethics if you have any doubts as to the applicability of the Template.

If you feel that the Template, or elements of it are not appropriate and you wish to use an alternate approach, please provide an explanation in your SPF, unless the explanation is obvious from the context.

Before completing the Template, please make sure that you have the most recent version by checking the Office of Research website.

## LANGUAGE LEVEL

Your Consent Form’s language level should be appropriate to the population of participants. For studies that involve recruiting members of the general population, a grade 8 reading level is recommended. This can be achieved by:

* Using short declarative sentences
* Avoiding technical terminology where possible, and explaining it where necessary
* Putting information in bulleted lists, tables or diagrams, where appropriate

## FRENCH, ENGLISH, AND OTHER LANGUAGES

French and English versions of the Template are available. Researchers are asked to complete the Template in English or French for review. Once the version submitted has been finalized, the researcher will normally be asked to translate the form into the other language. However, if there is reason to believe that participants will all be fluent in one or the other of the languages, a translation may not be necessary. Furthermore, if there is reason to believe that participants will not be fluent in English or French, other arrangements will have to be made. This may include translating the form into additional languages, or arranging for an interpreter to be present.

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**INFORMATION AND CONSENT TO PARTICIPATE IN A RESEARCH STUDY**

**Study Title:**

*State the study title as it appears in the SPF.*

**Researcher:**

*Please include the following:*

|  |  |
| --- | --- |
| *For Faculty Research:** *Faculty Member’s name*
* *Title, e.g. Assistant professor, associate professor etc.*
* *Academic department*
 | *For Student Research:** *Student’s name*
* *Level of studies and program, e.g. Master’s student in Communications Studies*
 |

**Researcher’s Contact Information:**

|  |  |
| --- | --- |
| *For Faculty Research:** *Concordia mailing address, phone number with extension, and e-mail address*
 | *For Student Research:** *Mailing address and phone number (students are encouraged to provide a Concordia address and phone number if they have one. Students should not normally provide a home address.)*
* *Concordia e-mail address*
 |

**Faculty Supervisor:**

*Delete this section for faculty research. For student research, provide the faculty supervisor’s name, title and academic department as described above.*

**Faculty Supervisor’s Contact Information:**

*Delete this section for faculty research. For student research, provide the faculty member’s Concordia mailing address, phone number with extension, and e-mail address.*

**Source of funding for the study:**

*State all sources of funding for the study.*

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You are being invited to participate in the research study mentioned above. This form provides information about what participating would mean. Please read it carefully before deciding if you want to participate or not. If there is anything you do not understand, or if you want more information, please ask the researcher.

**A. PURPOSE**

The purpose of the research is [ ]

*Succinctly explain why you are conducting the study, for example, to document the lived experience of a group of people, or to determine whether one approach to a problem is better than another. You may wish to provide some background information to put the research in context. However, the background information should normally be provided in simple terms, understandable to members of the general public. It should not include material cut and pasted from a grant application.*

*Do not describe the procedures here.*

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**B. PROCEDURES**

If you participate, you will be asked to [ ]

*Explain what participants will be asked to do as part of the study, including any screening procedures. Describe all research procedures, and how long they will take. For example:*

* *Complete a Montreal Cognitive Assessment. This is a 10-minute test that can detect mild problems with thinking and remembering. This test uses written and verbal exercises.*

*If there are many procedures conducted over multiple sessions, a bulleted list and/or a summary table might be the best way to provide this information.*

In total, participating in this study will take [ ]

*Provide an estimate of the total duration of participation. If this is already obvious from the information provided above, this statement can be deleted.*

As a research participant, your responsibilities would be:

*Describe anything that the participant is being asked to do outside of the procedures described above, for example, “to bring appropriate clothing for physical activity”. If the participant has no such responsibilities, this statement can be deleted.*

*If the research is taking place in the context of clinical care, include the following statements, filling in the blank as appropriate. Otherwise delete them:*

Some parts of the study are part of standard care, and they are done for your benefit. However, the following procedures are done for the scientific purpose of the study, and not for your benefit:

[ ]

You might have treatment options other than participating in the study. The researcher will explain them to you.

*If the study involves randomly assigning participants to treatment groups, include the following statement, filling in the blanks as necessary. Otherwise delete it.*

Participants will be assigned to one of the following groups: [ ]. The assignment will be random, like the flip of a coin. Your chance of being assigned to each group is [ ].

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**C. RISKS AND BENEFITS**

You might face certain risks by participating in this research. These risks include:

*State all reasonably foreseeable risks that could arise from participation. Even relatively minor risks should be included, for example, feeling uncomfortable discussing certain topics. To the extent possible, describe the risks in terms of their likelihood and severity, and if appropriate, what can be done to address such risks if they occur. Risks might include not only physical risks, but psychological, social, and financial risks.*

*If the research includes pregnant or nursing women, include the risks, if any, to the embryo, fetus, or nursing infant.*

*If the research entails risks to individuals other than participants, to communities or to organizations, these should be included in a separate statement.*

You might or might not personally benefit from participating in this research. Potential benefits include: [ ]

*Describe any direct benefits to participants, for example, the fact that they might receive information about their health, or insight into their personality. Do not include benefits to society, for example, the fact that the research is expected to advance our understanding of a particular phenomenon. If there are no direct benefits to participants, include the following statement instead.*

This research is not intended to benefit you personally.

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**D. CONFIDENTIALITY**

*The statements in this section are normally appropriate if the information is being gathered for a one-time study. If you intend to use the information for purposes that go beyond what is described in section A, or if you intend to share the information with individuals outside of the research team, a more elaborate statement will be necessary. Please consult with the Manager, Research Ethics, if this is the case. In any event, this section should forthrightly describe the following over the entire lifecycle of the research:*

* *The information that will be gathered*
* *Who will have access to it*
* *The degree to which the information will be identifiable when it is collected, when it is stored, when it is provided to others, and when it is published*
* *The physical and electronic safeguards used to protect it*
* *Provisions for destroying it when it is no longer needed*

We will gather the following information as part of this research: [ ]

*If it is obvious what information is being gathered on the basis of the Procedures section, this statement can be deleted. However, the consent form should normally describe what information is being gathered about participants, for example, demographic information, contact information, responses to surveys, opinions on particular topics. If information is being obtained other than by obtaining it directly from the participant, please mention it here. For example, if you intend to access their academic records or health records, include the following statement, filling in the blanks as appropriate:*

By participating in this study, you agree to let the researchers have access to information about [ ]. This information will be obtained from [ ].

We will not allow anyone to access the information, except people directly involved in conducting the research, and except as described in this form. We will only use the information for the purposes of the research described in this form.

*The following information should be included for information that is subject to audit by regulatory authorities such as Health Canada or professional orders. Otherwise it should be deleted.*

To verify that the research is being conducted properly, regulatory authorities might examine the information gathered. By participating, you agree to let these authorities have access to the information.

*Choose one of the following statements explaining the degree to which the information is identifiable when it is collected, and delete the remainder. Please ensure that this is consistent with the information provided in the SPF.*

The information gathered will be anonymous. That means that it will not be possible to make a link between you and the information you provide.

The information gathered will be coded. That means that the information will be identified by a code. The researcher will have a list that links the code to your name.

The information gathered will be identifiable. That means it will have your name directly on it.

We will protect the information by [ ]

*Please describe the measures taken to protect the information. For example, information stored on paper might be kept in a locked filing cabinet in the researcher’s office; electronic information might be protected in a password-protected file on the researcher’s hard drive.*

*Choose one of the following statements explaining the degree to which the information will identifiable when it is published. Please ensure that this is consistent with the information provided in the SPF.*

We intend to publish the results of the research. However, it will not be possible to identify you in the published results.

We intend to publish the results of this research, and we might include your name along with the information you provide in the publication.

We intend to publish the results of this research. Please indicate below whether you accept to be identified in the publications:

[ ] I accept that my name and the information I provide appear in publications of the results of the research.

[ ] Please do not publish my name as part of the results of the research.

We will destroy the information five years after the end of the study.

*A five-year retention period is generally recommended. However, a shorter period can be justified in some cases, and a longer period is required in certain cases. This statement can be modified accordingly.*

In certain situations, we might be legally required to disclose the information that you provide. This includes situations where [ ]. If this kind of situation arises, we will disclose the information as required by law, despite what is written in this form.

*If it is impossible that a “reportable situation” will arise by the nature of the research, delete this statement. However, if there is a chance, however small, of having to break confidentiality, this statement should be included. For example, reportable situations could include situations where the researcher learns that the participant intends to cause serious harm to him or herself or others, or situations of child abuse.*

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**E. BIOLOGICAL SAMPLES**

*This section applies only to research involving human biological material. If your research does not involve human biological material, please delete this section and re-number the remaining sections accordingly. Furthermore, this section is appropriate for one-time study with biological specimens. If you intend to store specimens for future studies, please consult with the Manager, Research Ethics.*

You will be asked to provide the following biological samples as part of the research: [ ].

*Describe the type of specimen, for example, hair or urine, and the amount to be taken.*

Taking these specimens involves [ ].

*Describe how the specimens will be obtained. For example, saliva samples might be obtained by swabbing the inside of the mouth.*

We will use these specimens for [ ].

*Describe the intended use of the samples.*

We will keep the specimens [ ]. After that they will be destroyed.

*State how long the samples will be kept and the location in which they will be kept.*

If we find anything that might be relevant to your health, we will [ ].

*Please explain your plan for handling clinically relevant information and incidental findings. Make sure this information is consistent with the SPF. This statement can be deleted if it is impossible that such findings will arise.*

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**F. CONDITIONS OF PARTICIPATION**

You do not have to participate in this research. It is purely your decision. If you do participate, you can stop at any time. You can also ask that the information you provided not be used, and your choice will be respected. If you decide that you don’t want us to use your information, you must tell the researcher before [ ].

*If it is impossible to ask that information not be used, delete the last two sentences.*

As a compensatory indemnity for participating in this research, you will receive [ ]. If you withdraw before the end of the research, you will receive [ ]. We will also reimburse you for the following expenses: [ ]. To make sure that research money is being spent properly, auditors from Concordia or outside will have access to a coded list of participants. It will not be possible to identify you from this list.

*If participants are being offered compensation, this statement should be deleted. Modify the statement as necessary, for example, to reflect the fact that participants might be entered in a draw for a prize.*

We will tell you if we learn of anything that could affect your decision to stay in the research.

There are no negative consequences for not participating, stopping in the middle, or asking us not to use your information.

We will not be able to offer you compensation if you are injured in this research. However, you are not giving up any legal right to compensation by signing this form.

*If there is a possibility that the results of the research will be commercialized, or the researcher is in a real, potential, or perceived conflict of interest, a statement to that effect should be added here.*

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**G. PARTICIPANT’S DECLARATION**

I have read and understood this form. I have had the chance to ask questions and any questions have been answered. I agree to participate in this research under the conditions described.

NAME (please print) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

SIGNATURE \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

DATE \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

If you have questions about the scientific or scholarly aspects of this research, please contact the researcher. Their contact information is on page 1. You may also contact their faculty supervisor.

*For faculty research, delete the statement about contacting the faculty supervisor.*

If you have concerns about ethical issues in this research, please contact the Manager, Research Ethics, Concordia University, 514.848.2424 ex. 7481 or oor.ethics@concordia.ca.