

**APPENDIX**

**LETTER OF INFORMATION / CONSENT**

**Note to Researcher:**

1. Please adapt this sample to match the needs of **your** specific study.
2. Before submitting this form, [delete all researcher instructions and sample wording in blue font that you aren’t using].
3. Remember to save this form in pdf format before uploading to your application in MacREM.

If you have questions about whether certain text should be included in your Letter of Information, please contact [ethicsoffice@mcmaster.ca](mailto:ethicsoffice@mcmaster.ca).

**[Study Title]**

**Principal Investigator: Student Investigator:** [If applicable]

Dr. Name

Department ofName Department of

McMaster University McMaster University

Hamilton, Ontario, Canada Hamilton, Ontario, Canada

**(905) 525-9140 ext. XXXXX (905) 525-9140 ext. XXXXX**

E-mail: (McMaster Address) E-mail: (McMaster Address)

**Co-Investigator**: [if applicable] **Co-Investigator**: [if applicable]

[Include full contact information as above] [Include full contact information as above]

**Research Sponsor**: [Delete if research isn’t funded.]

**Purpose of the Study:** [OR Alternate wording: **What am I (are we) trying to discover?**

[Describe concisely and in simple language the purpose of the research or the research question being asked. Avoid simply inserting the title of the study if it doesn’t clearly describe the purpose.]

You are invited to take part in this study on …. I (we) want to ……. I am (we are) hoping to learn…..I (we) also hope to find out….

**And/or**: [If applicable, edit and add.] I am doing this research for a course, thesis, dissertation, project under the supervision of [Supervisor’s name].

**And/or:** [If applicable edit and add.] This is a line of research that I hope to continue in the future and will use your data for this project as well as for future related studies.

**Procedures involved in the Research:** [OR Alternate wording: **What will happen during the study?**]

[Describe the procedures step by step, using simple language, short sentences and short paragraphs or bullets if appropriate. Put yourself in the place of the participant and describe the procedure as you might want it explained to you. Use the word “you” rather than the “the participant” and “I” or “we” rather than “the researcher(s)”. If scientific terms are unavoidable, they must be clearly explained. Details such as the length of time each part of the study will take, assignment to study groups, frequency of procedures, where participation will take place etc. should be provided. If the study involves an interview, indicate whether you will like to take handwritten notes supplemented by audio-recording the interview or both and insert the phrase “with your permission.” Provide 2-3 sample questions. Include those that you think the participant would find most sensitive. If feasible, attach the interview guide (the list of questions you will ask) for one-on-one interviews or focus groups.]

You will be shown…. You will be asked to do …. You might be asked to …. A XXXX will be attached to your body to monitor …. You will be asked to complete …… You will be assigned to…. I am going to talk about things like … I will be asking you questions about… I will also ask you for some demographic/background information like your age and education.

**Potential Harms, Risks or Discomforts:** [Alternate wording: **Are there any risks to doing this study?]**

[Describe to participants any reasonably foreseeable risks, discomforts, inconveniences that might occur, and how they will be dealt with as described in **Section 14** of your application form.]

[Wording For high risk research] You should be aware that there are risks when taking part in this study such as….

**Or**

The risks involved in participating in this study are minimal. You may feel uncomfortable with (anxious, uneasy about) …. You may find it stressful to….You may worry about how others will react to what you say….

**Or**

It is not likely that there will be any harms or discomforts from/associated with ….

You do not need to answer questions that you do not want to answer or that make you feel uncomfortable. I describe below the steps I am taking to protect your privacy.

**Potential Benefits** [Alternate wording: **Are there any benefits to doing this study?]**

[Describe what potential benefits to the community, to science, or to society at large, if any, may be expected from the research as described in **Section 14: Benefits** in the application.]

The research will not benefit you directly. I/We hope to learn more about…… I hope that what is learned as a result of this study will help us to better understand …This could help….

**Incentive/Payment or Reimbursement** [If applicable]

[If the participants will be compensated/reimbursed as described in **Section 13** of your application, indicate what the compensation will be, e.g., gift card, draw, e-money transfer, Sona credits. Include if compensation will be prorated depending on what has been completed, e.g., $5 for every 30 minutes up to $20. If there is no compensation for participants, this section of the letter should be removed.]

**Confidentiality** [Alternate wording: **Who will know what I said or did in the study?**]

[Review **Section 15** of your application to describe procedures to ensure confidentiality (i.e., how you will keep their information private) or anonymity (i.e., how you are ensuring that their identity will be known to no one, including you as the researcher). If confidentiality cannot be assured or guaranteed, indicate that this is the case. If participants want to be identified or your research warrants offering that option, or pseudonyms will be used, explain this clearly. Also provide information about the steps you are taking to maintain the security of the data while it is in your possession, the length of time you will be retaining it and what you will do with it once the study has been completed.]

**NOTE TO RESEARCHER:** [if you are using online video platforms for data collection – Zoom, Teams, Skype, etc. – then please refer to the [**MREB COVID-19 FAQ**](https://research.mcmaster.ca/ethics/mcmaster-research-ethics-board-mreb/mrebcovidfaqs/) and the [**Using Video-Conferencing Platforms in Human Participant Research**](https://research.mcmaster.ca/ethics/mcmaster-research-ethics-board-mreb/videoconferencing/)guide. These resources include language for the Letter of Information specific to communicating confidentiality and data security information to participants when using these online platforms to collect data.]

You are participating in this study confidentially. I will not use your name or any information that would allow you to be identified…No one but me [or other members of the research team such as the research assistant …] will know whether you were in the study unless you choose to tell them.

**Or**

Every effort will be made to protect your confidentiality and privacy. I will not use your name or any information that would allow you to be identified. However, we are often identifiable through the stories we tell. Please keep this in mind in deciding what to tell us.

**Or**

We are not collecting any directly identifying information. However, through the combination of demographic variables (e.g., department, gender, age) it may be possible to identify some participants. Please keep this in mind when deciding whether you want to participate and what questions you answer.

**Or**

However, since your group (community) is small, others may be able to identify you on the basis of references you make. Please keep this in mind in deciding what to tell us.

**Or**

[**For focus groups**]: I will undertake to safeguard the confidentiality of the discussion. I will ask the other members of the focus group to keep what you say confidential, but I cannot guarantee that they will do so. Please keep this in mind in deciding what to tell me.

**Or**

You are participating in this research anonymously. No one, including me, will know that you participated.

The information/data you provide will be kept in a locked desk/cabinet where only I will have access to it…Information kept on a computer will be protected by a password. Once the study has been completed, the data will be destroyed ….

**Or**

Once the study is complete, an archive of the data, without identifying information, will be maintained… [If applicable].

**Legally Required Disclosure:** [If applicable – remove this section if it is not necessary]

[Researchers will generally be required to reveal certain information if it is required by law (e.g., child abuse, public health risk, etc.). However, researchers involved in certain types of sensitive research (e.g., criminal activity / assisted suicide etc.) may choose to challenge a request for their data, in which case wording found in choice ii) below may be preferred.

**Note to Researchers:** Researchers are encouraged to consult with the MREB to discuss such issues that could pose greater than minimal risk to participants.

1. Although I will protect your privacy as outlined above, if the law requires it, I will have to reveal certain personal information (e.g., child abuse).

**Or**

ii) I will protect your privacy as outlined above. If legal authorities request the information you have provided, I will defend its confidentiality.

**Or**

1. If legal authorities request the information you have provided, I may be required to reveal it.

**Participation and Withdrawal:** [Alternate wording: **What if I change my mind about being in the study?**]

Your participation in this study is voluntary…It is your choice to be part of the study or not.…. If you decide to be part of the study, you can stop (withdraw) from the [interview, survey, etc.] for whatever reason, even after giving consent or part-way through the study or up until **[insert specific date – e.g. April 15, 2018]**, when I expect to be submitting my [thesis, dissertation or manuscript.]

If you decide to withdraw, there will be no consequences to you. In cases of withdrawal, any data you have provided will be destroyed unless you indicate otherwise. If you do not want to answer some of the questions you do not have to, but you can still be in the study.

**Or**

[Wording for withdrawal from a focus group] If you want to stop being in the focus group you can stay and simply stop talking or you can leave, but it will not be possible for you to pull out your data from the flow of the conversation because of the interconnected nature of this type of group discussion where a person’s comments can stimulate the sharing of comments made by others in the group.

**Or**

[Wording for withdrawal from research when the researcher knows the participant’s identity] You can withdraw from this study up until [**insert specific date – e.g. April 15, 2018**], when I expect to be submitting my thesis, dissertation or manuscript.]

**Or**

[Wording for withdrawal from an anonymous survey] Once you have submitted your responses for this anonymous survey: your answers will be put into a database and will not be identifiable. This means that once you have submitted your survey, your responses cannot be withdrawn from the study because I (we) will not be able to identify which responses are yours.

Your decision whether or not to be part of the study will not affect your continuing access to services from …. [name the organization, office, service or person, if applicable or remove if not applicable.]

**Information about the Study Results:** [Alternate wording: **How do I find out what was learned in this study?**

I expect to have this study completed by approximately [**insert month, year**]. If you would like a brief summary of the results, please let me know how you would like it sent to you.

**Or**

A summary of the results will be posted at …… If you would like to receive the summary personally, please let me know how you would like me to send it to you.

**Questions about the Study:** If you have questions or need more information about the study itself, please contact me at:

|  |
| --- |
| [Insert researcher’s email address,  telephone number or  Mailing address, as appropriate]. |

**[Note to Researcher: The following statement is required.]**

This study has been reviewed by the McMaster University Research Ethics Board and received ethics clearance. If you have concerns or questions about your rights as a participant or about the way the study is conducted, please contact:

McMaster Research Ethics Secretariat

Telephone: (905) 525-9140 ext. 23142

C/o Research Office for Administrative Development and Support

E-mail: [ethicsoffice@mcmaster.ca](mailto:ethicsoffice@mcmaster.ca)

**CONSENT**

[**Note to Researcher:** Keep the Letter of Information and this consent portion together as one document. When obtaining written consent, make certain that you bring two copies: one for your records and one for the participant to keep.]

* I have read the information presented in the information letter about a study being conducted by [**Insert researcher’s name(s)],** of McMaster University.
* I have had the opportunity to ask questions about my involvement in this study and to receive additional details I requested.
* I understand that if I agree to participate in this study, I may withdraw from the study at any time or up until **[insert specific date – e.g., April 15, 2018]**

**[OR if an anonymous study]** I understand that if I agree to participate in this study, I may withdraw from the study at any time until I submit my responses, but once my responses have been submitted, they cannot be withdrawn due to the anonymous nature of the study.

* I have been given a copy of this form.
* I agree to participate in the study.

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of Participant (Printed) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Consent Questions:**

**Note to Researcher:**

1. **Adapt, use, or delete** the following questions based on the particular needs of **your** study.
2. If you are using an **Oral Consent Log** and/or an **Oral Consent Script**, these questions should be identical to the columns of your Consent Log and to the questions at the bottom of your Oral Consent Script.

If yes,

1. Would you like a copy of the study results? If yes, where should we send them (email, mailing address)?
2. Would you like to be entered in a draw for gift card, prize? How do you prefer to be contacted?
3. Where can we send your incentive? [e.g., mailing gift card, e-transfer, e-gift card]
4. Do you agree to [audio and/or video] recording?
5. Do you wish to be identified in the report/results?

[For studies where it is difficult to guarantee confidentiality due to sample size, participants are public figures or hold unique positions in society/their organization, or study results will be disseminated in audio or video format. This may not be just a “yes” or “no” answer but more of a discussion about the participant’s comfort level.]

1. Do you agree to be contacted for a follow up [interview/survey/focus group/experiment/etc.]? How do you prefer to be contacted?
2. Do you agree to allow your [anonymized/identifiable] study data to be stored and used for future research as described in the Letter of Information?
3. Do you agree to be added to a recruitment database to be contacted for future research? How do you prefer to be contacted?
4. Do you agree to allow the use of your anonymized transcript data for training purposes within a course?