

INFORMED CONSENT

How to Obtain Informed Consent

Participants must be given enough information about the project in order to make a fully informed decision about their participation. This information typically is shared with potential participants through an information letter and consent form.

General Points:

1. The language in your information letter needs to be clear and free from jargon. Generally, a grade 6-8 literacy level is best to ensure that the information is fully understood.
2. A child under 18 years of age should be given the opportunity to provide his/her assent to participate and may refuse to participate even if the parent/guardian has provided their consent.
3. Provide a copy of the consent form to the participant so that they have a record of what they signed as well as your contact information.



Generally, these are the components of an information letter and consent form:

Introductory Information:

- Title of research project
- Research organization and principal researcher. Include team members' names if they will have contact with participants.
- Who is funding the research, i.e., if it's a grant or an external agency such as the Ministry or ETFO or the Health Unit. This tells participants something about the nature of the research.
- The purpose of the research – Describe the project briefly and why you are doing it.
- Why you are inviting the person/child to participate.
- That participation is completely voluntary and they can withdraw from the project at any time and request that their data be withdrawn as well.
- That there are no repercussions for withdrawing.
- If the research involves a form of data collection that asks questions of participants (e.g., questionnaire, interview, focus group), state that the participant can choose not to answer questions if they don't feel comfortable answering.

What participants will be asked to do:

- A description of how the research will be carried out.
- How much of the participant's time will be required.
- If you are planning to digitally record the participant, state that here.

What will be done with the data you collect:

- State how long the data will be retained and how it will be safeguarded (e.g., survey documents or video files will be kept in a locked filing cabinet in the researcher's office or password protected in a file on the researcher's secure network drive for a period of 2 years and then properly destroyed.)
- How (if) you will let participants know about the research results. A short summary is fine.

Risks / Benefits:

Typically, participants are informed of benefits or risks of participation. It can be a benefit if they learn something through their involvement. It can be a risk if there are questions that could make them uncomfortable.

Compensation / Expenses:

Sometimes participants are reimbursed for their time/mileage or given an appreciation gift such as a gift card. That needs to be stated here if applicable.

Contact Information:

- If you have any questions about this study, please contact:

(give full contact information here)

Confidentiality / Publication of Results:

- Include information about what confidentiality and/or anonymity participants can expect. State how/if you will remove identifiers from materials, who will have access to the original documents/files and the de-identified documents/files.
- State the limits on the confidentiality you will provide, if appropriate. For example, if questions in a survey could trigger a child to disclose abuse or suicidal ideation, it must state that the researchers are legally obligated to report such disclosures to the appropriate authorities/agencies.
- Participants must be told in advance if you plan to use any of the research data to publish a paper, present at a conference regardless of whether or not the participants are anonymous. If you aren't sure, sometimes it is best to state that the findings might be used to share at conferences or in publications, then you have the choice to publish or share afterward. If you do not include this, you cannot use the data to publish or present at conferences/workshops.

For Focus Groups, you should consider adding a statement informing participants that although you ask for declarations of confidentiality from all participants, you cannot control, ultimately, what others do with the information they hear in a focus group.

Consent Form "DON'TS":

Do not state that the project has been approved by a Research Ethics Board. This makes it sound like the research is guaranteed to be safe and may influence participants' decision making.

Do not guarantee anonymity. No one can guarantee anonymity. You can only do your best to remove identifiers and change small details that, put together, could lead someone to guess who the participant is.

For further information, consider the following:

The 3,4,5's of Informed Consent,

<http://cconley.ca/2012/09/20/the-345s-of-informed-consent/>

Privacy Laws in Ontario, MFIPPA: <http://ow.ly/qkDL7>

PIPEDA: <http://ow.ly/qkDVv>

Education Act: <http://ow.ly/qkDZj>



Example: Information Letter and Consent Form

INFORMATION LETTER

Introduction

You are invited to participate in a survey conducted by the ABC company in partnership with researchers at the University of North Dakota. John Smith is the Director at the Centre for Research in the Faculty of Health Services at the University of North Dakota; Dr. Pamela Eragon is an Associate Professor, and Dr. Jen McCalf a post-doctoral researcher in the same faculty.

This survey looks at how students can be provided with more opportunities for positive physical activity during the school day. You are being asked to participate because you are an elementary teacher.

Purpose of the study

When children participate in positive physical activity on a daily basis, the impacts are monumental. Many healthy living studies have been conducted in both Canada and the U.S., however, there are not many studies that focus on how to integrate positive physical activity into the daily school schedule. Data is urgently needed to inform policy on how best to do this. The aims of this study are to learn about how positive physical activity is currently being integrated into the school day and what further can be done to see this integration on a larger scale.

If you agree to participate

If you agree to participate in this study you will be asked to complete a survey. The survey will be provided to you by the researcher. We estimate that it will take you about 10-30 minutes to complete the survey. You have the flexibility to complete the survey over a week's time. At that point, the researcher will return to the school to collect the completed surveys. If you choose to participate, please seal the survey in the envelope provided and place it in the box designated in the staff room by the date on the survey.

Compensation

In appreciation for your time, once you complete the survey, you will be given the option to provide your personal information so that you may be entered in a draw for a tablet computer. Entry in the draw is optional and your personal information will not be linked with your survey data. It will be kept separate and only used for the draw.

Confidentiality

All information collected for the study will be anonymous. The information will be used for research purposes only, and no information which could identify you will be used in any publication or presentation of the study results. Unless you choose to tell them, no one, including your employer, supervisor, co-workers or union representatives will know whether or not you have completed the survey. Your decision to participate will not affect your employment or union status. Survey data will be stored at the University of North Dakota on password-protected computers. Hard copies of the surveys will be destroyed directly after the information is inputted into the computer. Only members of the research team will have access to the data. Electronic data will be destroyed after 7 years.

Potential Risks & Benefits

We do not anticipate any risks to your involvement. By completing this survey, you may learn about positive physical activity for children during the school day. However, it is possible that you may not directly benefit from participating in this research.

Voluntary Participation

Participation in this study is voluntary. You may refuse to participate, refuse to answer any questions or withdraw from the study at any time without any penalty. Neither your employer, nor your union will know if you decide not to participate or not to answer questions. However, if you withdraw from the study, any data you entered into the survey cannot be removed, since it is anonymous.

Consent

We require your informed consent to participate in this research. If you choose to participate, please complete the attached consent form and return it to the researcher.

Questions

If you have any questions about the conduct of this study or your rights as a research participant you may contact the Office of Research Ethics, University of North Dakota at 717-456-9845 or ethics@und.com. If you have any questions about this study, please contact John Smith at 717-786-2005 (jsmith@und.com) or Dr. Pamela Eragon at 717-453-9823 x12678 (peragon@und.com).

Please keep this copy for your records.

Project Title: Students Becoming More Active at School

Principal Investigator: John Smith, Director, Centre for Research, Faculty of Health Services,
University of North Dakota

CONSENT FORM

I have read the Letter of Information, have had the nature of the study explained to me and I agree to participate. All questions have been answered to my satisfaction.

Participant’s Name (please print):

Participant’s Signature:

Date:

Person Obtaining Informed Consent (please print):_____

Signature:_____

Date:_____

Please return this completed form to the researcher.