**Aurora College REC Guidance for Applications for Ethics Review: Guide for Drafting the Informed Consent Form**

# General Comments

In general, principle investigators (PIs) submitting an Application for Research Ethics Review to the Aurora College Research Ethics Committee (REC) must include a written consent form with their application and explain the consent process that will be used during their research. The information in this guidance document is designed to briefly describe the principle elements usually found in a written consent form and to help researchers in producing their consent form to better meet the requirements of the REC.

Additional information may be required for consent forms used in certain research projects. If information is not needed in a consent form of a particular research project, the PI should explain the reason for this situation to the REC.

* The consent form should be dated and printed on the appropriate letterhead
* The readability level should be determined by taking into consideration of the type of population studied (plain language description)
* The information letter should be written in second person (“you”, “your”, “yours”)
* The consent form should be written in first person (“I”, “my”, ”mine”)
* Include an information sheet that the participant can take home that provides the full project details, risks and benefits, researcher information and any other information the participant may need to reference in the future, separate from the statements of understanding and signatures usually found on a consent form. Alternatively, the PI can offer to give each participant a copy of the full signed consent document, however the PI should consider the logistics of copying at the research site and consider whether it is possible to offer the participant their copy to keep immediately after signing.
* Create separate consent documents for different types of data collection (eg. interviews and focus groups) and different population sub-groups, as necessary (eg. students and instructors)

# Title of the Research Project

* The title must be the same as the one provided on Page 1 of the application form.
* The title should be used consistently throughout the research project documentation and communications with the REC
  + If the title is very complicated and a plain language title is more appropriate for participant documents, please be sure to explain this within your application

# Principal Investigator

* Include the name and contact information for the principal investigator only – including other members of the research team is generally discouraged (to reduce revisions, should there be turnover in research personnel)
* Provide clear instructions for how to contact the principal investigator
* Include list of sponsors if applicable

# Purpose of the Research

* This section should answer the question: "Why conduct this research project?"
* Describe briefly the purpose of the study

# Description of the Research

This section should answer the questions: "How will the study be conducted and how will the research participants be involved?"

* Describe the type of population that is being studied
* Mention that this is an invitation to participate in this study and explain why they are being invited to participate
* Include a statement that the individual’s participation to the research is voluntary
* Describe the Inclusion/exclusion criteria of potential research participants, if appropriate
* Provide a brief step-by-step description of the proposed research as it will be experienced by the research participant (each stage and approximated time it will take)
* If participants are required to undergo specific testing as part of the research, this must be explained - indicate the frequency and duration of specific testing, as well as the duration of the entire study
* Include the following statement: "If changes are made to the study or new information becomes available, you will be informed"
* If a questionnaire is to be completed, provide a description of the questionnaire, how long it will take to complete and that the participants have a choice of not answering any questions or withdrawing at any time
* If the study involves taking photographs, videotaping, sound recordings or note-taking, please include a specific section of the form to provide consent for these activities
* If the study includes a focus group, the PI should put in place a procedure to caution participants about the limits on confidentiality
* If future use of the research data beyond the current study is anticipated, this should be explained (for e.g., subsequent use of videos, depositing data in an accessible database, etc.)

# Access to Research Information

* Provide information regarding who will have access to the data collected
* Provide information regarding retention of data (including audio and video tapes) and schedules for their disposal
* State how, if at all, participants will be informed of the results of the research
* Indicate on the consent form that "you may refuse to participate or may withdraw at any time".
* Describe what will happen to data that’s been collected in the event a participant withdraws from the study. Is there a timeframe within which they can do this (eg. before data analysis, before the final report is completed)? If yes, please indicate this on the consent form. If not, the researcher will be required to provide a rationale for not providing the participants with a choice of removing his/her data from this research and any future research.
  + If future use of the data is anticipated, you may wish to include the following question: Do you agree for your contribution to be used for future research? Yes  No  (if they say no, then you may not retain the data for future research projects)

# Potential Risks, Harm, Discomforts or Inconvenience

If there is no known harm to the participants, this should be stated in one of the following ways: "There is no known risk or harm associated with participation in this study." Consider also any possible unintended harm that may come from participating in the study.

If there are known risks or harms to the participants, state clearly:

* + all foreseeable risks and their likelihood
  + the potential harm participants may experience
  + current knowledge regarding the probability of the occurrence of the harm
  + all actions taken to mitigate risk

# Potential Benefits

* + If participants will not benefit directly from participation in this study, the following statement should be included: "You will not benefit directly from participating in this study."
  + If participants might benefit directly from participating in this study, this should be stated and the potential benefits should be described
  + If society in general or individuals with a similar condition might benefit from the results of this study, this should be explained

# Confidentiality

In instances where it will not be possible to assure complete confidentiality, the limits on this obligation should be carefully explained (for e.g., focus groups, suspected child abuse and reportable diseases by law).

For focus groups, the Principal Investigator should consider adding a statement of the potential harm that could exist if confidentiality is violated by someone participating in these focus groups. The PI is required to explain that the researchers are capable of promising confidentiality of information but can't promise that the other participants will observe each other’s privacy.

# Reimbursement, Compensations and/or Indemnity

* Participants or their parents may be offered money for reasonable out-of-pocket expenses (e.g. transportation costs, meals, baby-sitters). In addition, participants or their parents can be reimbursed for loss of wages or be offered an honorarium for sharing their knowledge or expertise. Under no circumstances should payment be offered for harm or discomfort.
* Explain what will happen to the compensation if the participant withdraws from the research (e.g. pro-rated reimbursement.)
* If a thank-you gift is to be presented after completion of the study, this should not be mentioned in the research consent form or the recruitment material to reduce the risk of undue inducement
* If honoraria is offered for participation, the amount must be justified and should not offer undue inducement to participate in the study
* If honoraria is offered, there should be a protocol in place for the possibility that a participant may withdrawal (do they keep the honoraria? Is it pro-rated for the length of the study? How might these factors influence someone’s participation?)

# Participation

* If there are parts of the research study in which a research participant could choose not to participate this should be clearly explained
* The following statements must be included: "Participation in research is voluntary. If you choose to participate in this study, you may withdraw at any time."
* If they do not wish to participate, they do not have to provide any reason for their decision not to participate nor will they lose the benefit of any assistance or services to which they are entitled or are presently receiving
* In the rare instances where it will not be possible for participants to withdraw, the limits on the right to withdraw should be carefully explained to the research participants
* Parents of participants should be made aware that assent may be required from their child

# Waiver of Rights

Investigators are prohibited from seeking or obtaining waivers of participant's legal rights.

# REC Contact Information

The following statement or a similar statement should be added in the consent form:

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

[Name, area code and phone number of the Investigator]

If you have questions about your rights as a research participant, you may contact:

Aurora College Research Ethics Committee   
50 Conibear Cres.   
Fort Smith, NT X0E 0P0  
Phone: 867-872-7084  
Facsimile: 867-872-5024  
Email: [chairrec@auroracollege.nt.ca](mailto:chairrec@auroracollege.nt.ca)

# Consent

The following is an example of the statements of understanding that participants agree to on the signature page of the form (check boxes, initials, statements, or other formats may be used):

By signing this form, I agree that:

* The study has been explained to me.  Yes  No
* All my questions were answered.  Yes  No
* The possible harm and discomforts and possible benefits (if any) of this study have been explained to me.  Yes  No
* I understand that I have the right not to participate and the right to stop at any time.  Yes  No
* I understand that there will be no consequences for me if I refuse to participate.  Yes  No
* I have a choice of not answering any specific questions.  Yes  No
* I am free now, and in the future, to ask any questions about the study.  Yes  No
* I understand that there may be a slight risk for me while giving blood and that there may be minimal chance of infection. These discomforts are brief and transient. Yes  No

[A statement of understanding should be included for any specific risk or harm participants will face]

* I have been told that my personal information will be kept confidential.  Yes  No
* I understand that no information that would identify me will be released or printed without asking me first.  Yes  No

[This statement can be adapted or excluded, depending on the confidentiality terms of the study protocol]

* I understand that I will receive a signed copy of this consent form.  Yes  No

# For future research projects (if applicable)

* I agree that my data/samples may be used for future testing in similar research projects.  Yes  No

I hereby consent to participate in this study:

Name of Participant:

Signature:  
Date: