St. Lawrence College

REC-P Guidelines for creating an Informed Consent Document

The goal of the informed consent process is to provide potential participants enough information about the research so they can make a free and informed choice about whether they would like to participate in the research. Creating a consent document for research participants is **one part** of the informed consent process. Participants must be given adequate time to read the informed consent document, have it explained to them (if necessary), and be given the opportunity to have all of their questions answered. The "informed" part of the consent process means that the participants **understand** what their participation in the research will involve and what the risks are if they participate.

Since the primary purpose of the informed consent document is to provide information to potential research participants, informed consent forms must be clear and easy to understand. This means using simple, short sentences and using lay language. The target grade level for a consent form should be about Grade 6 to 8. The student can use the Word tool, Flesch-Kincaid readability (or grade) level, to determine the reading level of your informed consent form. Other layout conventions can also make providing the information in the informed consent form easier to understand.

Some suggestions for making a clear consent form:

- **Simple lay language** (explain technical terms, acronyms, and jargon).
- Use one person and verb tense throughout the document – preferably second person (i.e., "you") and in an active (not passive) tense.
    - ⇨ However, it is preferable to use first person "I" for the signature block section (e.g., "by signing this consent form…I understand…").
- Use point form, lists, or tables to simplify information for complex procedures or schedules.
- All the information required by the participant should be in **one** informed consent form document. Avoid attachments or other information forms

Some suggested format standards include, but are not limited to:

- A minimum of 12-point type size
- Sans serif font (such as this one, Arial) as opposed to serif fonts (like Times New Roman)
- Upper and lowercase (not ALL CAPS WHICH ARE HARDER TO READ)
- **Bold** type to emphasis necessary phrases or words
- Headings, small paragraphs, and spaces between the paragraphs
- More space above headings and subheadings than below them (giving a stronger visual link between the heading and the relevant text)
- Lots of white space to keep a page from being cramped and overwhelming
- At least 1/2 inch to 1 inch of white space around the margins of the page

- Use page numbering in the top right hand corner.

As well, for ethical reasons, consents must contain certain important elements. The required elements for most consent forms include, but are not limited to:

1. A statement that the study involves research, including:
    - The research purpose
    - Proposed use of data collected
    - Identification of the researchers and contact information
    - A statement regarding obtained ethical clearance
    - Identification of the sponsor (if applicable)

2. A list of foreseeable risks and potential benefits, including:
    - Explanation of measures used to treat/correct any foreseeable discomforts or harms
    - Explanation of measures to mitigate risk (i.e., plan if something goes wrong)
    - Explanation of measures to minimize confidentiality risks
    - Statement that, if applicable, there are no direct benefits to the participant
    - Benefits to society in general, if applicable
    - Reimbursement, compensation or honorarium should **not** be listed as a benefit

3. A statement describing the extent to which confidentiality will be maintained, including:
    - Information about what data will be collected
    - How data from the research will be stored and protected
    - How data from the study will be destroyed, and after what time period
    - How data will have identifiers removed, if necessary
    - What data will be used for publications (i.e., only non-identifying) and where it will be presented (e.g., in thesis and Behavioural Psych Poster)

4. Requirements of the study participants, including:
    - Duration and frequency of research related tasks
    - Nature of research tasks and procedures
    - Explanation of the responsibilities of the participant

5. A statement that participation is voluntary, including:
    - Participants will not be penalized or experience any negative consequences in any way if they do not take part
    - Explanation of how participants can withdraw at any time without reason

- Explanation of how participants can withdraw their data if they choose to withdraw from the study (explain if this is not possible if data is collected anonymously). State a realistic amount of time for withdrawal (e.g., up to 1 month after completion of participation)

6. A statement clearly distinguishing between who to contact for information about the study and who participants can contact if they have concerns about their rights as research participants (i.e., SLC Research Ethics Board).

The consent form submitted for Research Ethics Board (REB) review should be in its final form (as it will be seen by the participant), including:

- Letterhead with current SLC logo
- Correct spelling and grammar, including definitions of any acronyms
- Identifiers on the consent document (version date or number), preferably in the footer. When re-submitting any revisions to the consent form, change the version date/number and highlight all changes clearly.

It is your responsibility for ensuring that the consent form is understandable and complete. If you have any questions, please feel free to ask for assistance by emailing the Research Services Officer, Anthony Wright at awright@sl.on.ca.

Sample Consent #1

Project title: include same full title as provided on the application

Sample: The "Go Goddess" Program: A Prevention Program to Enhance Self-esteem and Self-efficacy in a Group of High-Risk Young Women.

Principal Investigator: student name
Name of supervisor: supervisor name
Name of Institution: St. Lawrence College
Name of institution/agency: *Agency X*

Invitation

You are being invited to take part in a research study. I am a student in my 4th year of the Honours Bachelor of Behavioural Psychology at St. Lawrence College. I am currently on placement at the _____ *(name of agency)*. As a part of this placement, I am completing a research project (called an applied thesis). I would like to ask you for your help to complete this project. The information in this form will help you understand my project. Please read the information carefully and ask all the questions you might have before you decide if you want to take part.

Why is this research study being done?

[*Use simple and clear language describing what you hope to accomplish with the research (ie. what is the question you are trying to answer?). Use layperson terms to explain any complex ideas. Write out any acronyms.*]

Sample language: My project is on the "Go Goddess" program – a program that is meant to help young women increase their self-esteemby learning about their interests, their friends, and themselves. I have created a questionnaire to see if the group has been helpful to you. We believe this group is useful to young women. We want to know

what parts of the program were most helpful to you. This will help us make sure this program is successful now and in the future. Your opinions and thoughts are important and I am asking for your help to rate this program by asking you some questions.

What will you need to do if you take part?

If you choose to take part in this study you will be asked to_____

[*Use simple and clear language to describe what participants will have to do to take part, including detailed information about the location, timing and length of the session and/or intervention. Information about what you are asking the participant to do and how long the activity will take to complete.*]

Sample language: If you choose to take part in the study, you will be asked to take part in 8 sessions of the Go Goddess program. The sessions will be held on Monday afternoons at Agency X and last about 1 hour. The session will be run by myself and a supervisor from Agency X. At the first session, before you start the program, you will be asked to fill out a questionnaire that will take about 20 minutes to complete. At the end of the session each week, you will be asked to fill out a shorter questionnaire that will take about 5 minutes to complete. At the end of the program, you will be asked to complete a longer questionnaire that will take about 20 minutes to complete.

What are the potential direct benefits of taking part? *(if applicable)*

Benefits of taking part in this research study may include _____

[*If there are potential direct benefits to the participant (there may be none), these should be described as accurately as possible. This description should include relevant information about the nature of the potential benefit(s) (how important are these benefits?) and the probability of occurrence (how likely is it that the potential benefits will occur?) If there are no potential benefits to the prospective research participant, this must be stated explicitly (e.g., "You will not benefit directly from your participation in this study.")*]

Sample language: The potential direct benefits of participating in this project may include increasing your self-esteem.. *When direct benefits are not clear, it is good to acknowledge that the participant is helping you. For example: "Although there are no direct benefits from participating in this study you may appreciate knowing that you are helping me with my thesis research that will enable me to obtain my degree."*

What are the potential benefits of this research study to others? (*if applicable*)
The potential benefits of this research study to others may include

_____

[*If there are anticipated benefits to society (e.g., advancing scientific knowledge) or a particular group (e.g., advancing understanding about a particular group or guiding public policy), these should be clearly stated*.

Sample language for public benefit: Information from this project may also be used to help improve the "Go Goddess" program for other young women in the future.

What are the potential disadvantages or risks of taking part?
Risks from taking part in this research study are minimal but may include

_____

[*Risks can include physical or emotional stress, threat to personal safety, jeopardy to social position and loss of time (i.e., from work) required to participate in the research*.]

Sample language: If there are no known risks you can state: "There are no known risks associated with participating in this research project." *Or you can state: "*The risks of participating in this project are minimal. Some of the questions may make you feel uncomfortable."

What happens if something goes wrong?
[*What is the plan if participants have experience something negative during the research? How will the researcher help rectify this and/or mitigate this risk? Does the*

agency have guidelines to follow if something goes wrong? If parent/guardian/alternative caregiver is consenting for the participant, how will they be informed that something went wrong?]

Sample language: Everybody is different and if you do have any strong reactions to the program or questionnaires, you may talk to me, your counsellor, or the "Go Goddess" facilitator, [XXXXXX].

Will the information you collect from me in this project be kept private?

[**1**. *All information and data collected from participants, including consents, must be kept in a locked cabinet, or encrypted on a computer that is password protected. Data: Include information about where the data will be kept (usually the agency) and the* length *of time that the data will be kept (SLC policy is 7 years; if the agency's policy is longer, it should be followed). Consents: Include information about where the consents will be kept (usually SLC, but your agency may want to keep the consents or copies of the consents) and the length of time that the consents will be kept (i.e., 10 years, and if your participants are under 18, 10 years from the participants' 18th birthday)* ***2****. In addition, describe any other procedures in place to ensure confidentiality and privacy (i.e., using anonymous data, de-identified data, that is, removing identifiers from data, or anonymized data, that is, destroying the participant identification code key after data has been de-identified so that re-identification of participants in the future is impossible).* ***3****. As well, state that participants will not be identified by name in reports, publications, presentations etc.*..]

Sample language: We will make every attempt to keep any information that identifies you strictly confidential unless required by law. You will be assigned a code number to enter on the questionnaires and your name will not be used. Informed Consent Forms will be stored securely at St. Lawrence College for 10 years [10 years after your 18th birthday if you are now a minor]. All other research data will be stored securely at the agency for 7 years, after which time the data will be destroyed. The results from the research are part of my thesis and will be made available at the St. Lawrence College

library. They may also be published in professional journals or presented at professional conferences, but any such presentations will be of general findings and will never breach individual confidentiality.

Do you have to take part?

Taking part is voluntary. It is up to you to decide whether or not to take part in this research project. If you do decide to take part, you will be asked to sign this consent form. If you do decide to take part in this research project, you are still free to stop at any time, without giving any reason, and without it (e.g., negatively impacting your experience or the services you receive at this agency). If you decide to stop, please speak to me or my supervisor. [*If applicable: If you choose not to take part in this study, you can still continue to use the services at Agency X. If you choose to withdraw from the study, you can ask that your data not be used if you wish. It is good to give a reasonable amount of time for withdrawing one's data, for example, one month after the collection of the data. If data is anonymous then clearly withdrawing one's data is not a possibility and this needs to be communicated instead.*]

Contact for further information

This research project has received ethical clearance from the Research Ethics Committee for Behavioural Psychology (REC-P) under the authority of the St. Lawrence College Research Ethics Board (SLC-REB) [*if applicable: and at Agency X's REB*]. The project was developed under the supervision of _____, my supervisor from St. Lawrence College. I appreciate your cooperation and if you have any additional questions, feel free to ask me, [student name] _____ (*student@sl.on.ca*). You can also contact my College Supervisor [College Supervisor's name] _____ (*supervisor@sl.on.ca*). If you have concerns about the way this research is being conducted or about your rights as a participant you may contact the SLC-REB Chair at reb@sl.on.ca .

Consent

If you agree to take part in this research project, please complete the following form and return it to me as soon as possible. A copy of this signed document will be given to you for your own records. The original will be retained at the agency.

By signing this form, I agree that:

- ☐ The study has been explained to me.
- ☐ All my questions were answered.
- ☐ Possible harm and discomforts and possible benefits (if any) of this study have been explained to me.
- ☐ I understand that I have the right not to participate and the right to stop at any time.
- ☐ I am free now, and in the future, to ask any questions I have about the study.
- ☐ I have been told that my personal information will be kept confidential.
- ☐ I understand that no information that would identify me will be released or printed without asking me first.
- ☐ I understand that I will receive a signed copy of this consent form.
- ☐ I understand that the data from this study will be presented at the St. Lawrence College Behavioural Psychology Poster Gala, and may be reported at other conferences or published in a scientific journal. No identifying information will be included in these reports.

I hereby consent to take part.

Participant Name	Signature of Participant	Date

Student Printed Name	Signature of Student	Date

Sample Consent #2

Project title: A creative writing program to reduce stress and anxiety in children
Principal Investigator (Student):
Supervisor:
Institution: St. Lawrence College
Name of School: [Placement name]

Invitation

Your child is being invited to take part in a research study. I am a student in my 4th year of the Behavioural Psychology program at St. Lawrence College. I am currently on placement at [*placement name*]. As a part of this placement, I am completing a research project (called an applied thesis). I would like to ask you for your child's help to complete this project. The information in this form will help you understand my project. Please read the information carefully and ask all the questions you might have before you decide if you want your child take part.

Why is this study being done?

This project uses expressive writing as a way to help with stress and anxiety. Expressive writing involves journal writing to connect events with emotions. We believe this program will be helpful by helping children manage their emotions. Your child's opinions and thoughts are important in this project.

What will your child need to do if s/he takes part?

If you choose to allow your child to take part in this study s/he will be asked to meet with me (one-on-one) for one hour at lunch. We will talk about expressive writing and your child will complete a short questionnaire (about 20 minutes) about his/her level of stress. We will then meet twice a week (for about 45 minutes) during their lunch hour at school for 8 weeks. During this time, your child will be writing about different stressful events occurring in their life. We will discuss their writing at each session. Your child will assess their stress level both before and after writing. At the end of the 8 weeks, your child will complete a short questionnaire (about 20 minutes) to help evaluate the

program.

What are the potential benefits to your child if they take part?

Potential benefits of taking part in this research study may include your child learning more about him/herself. Your child may improve with how s/he manages their emotions.

What are the potential benefits of this research study to others?

The potential benefits of this research study to others may include improving the expressive writing program that may help other children manage their emotions.

What are the potential disadvantages or risks to my child if they take part?

Risks from taking part in this research study are minimal but may include feeling sad, angry or upset about the subject of their writing.

What happens if something goes wrong?

Every individual is different. If your child has a strong reaction towards any of the questions or writing, your child may speak further with myself or to the school counsellor, [name]. If your child becomes uncooperative during the program sessions, we will take a short 5-minute break at a preferred activity (e.g., reading a book, playing a game).

Will the information you collect from my child in this project be kept private?

We will make every attempt to keep any information that identifies your child strictly confidential unless required by law. No names or identifiers will be used. Your child will be assigned a code number to use on the questionnaires. The consent forms, my project notes and completed questionnaires will be kept in a locked filing cabinet at the [*placement name or SLC*] for 10 years past your child's 18th birthday. The computer files with the study data will be kept in a password protected file on a secure, password protected computer. All study documents and results will be kept securely for 7 years at [*placement name or SLC*] and then they will be destroyed. Your child's name or other

identifiers will not be used in any reports, publications, or presentations resulting from this project.

Does my child have to take part?

Taking part is voluntary. It is up to you to decide whether or not to allow your child to take part. I will also ask your child if they want to take part. If your child does not want to participate in this project, they will not be made to do so. If you decide to allow your child take part, you will be asked to sign this consent form. If you do decide to allow your child to take part in this project, you and/or your child are still free to stop at any time, without giving any reason, and without negatively impacting your experience or the services your child receives at this agency. If your child stops taking part, please have your child tell their counsellor, [name] or me.

Contact for further information

This research project has received ethical clearance from the Research Ethics Committee for Behavioural Psychology (REC-P) under the authority of the St. Lawrence College Research Ethics Board (SLC-REB) [*and list other required approvals, if any, for example, and Agency X's REB*]. The project was developed under the supervision of [College Supervisor name]_____, my supervisor from St. Lawrence College. I appreciate your cooperation and if you have any additional questions, feel free to ask me, [student name]_____ (*student@sl.on.ca*). You can also contact my College Supervisor [College Supervisor name] _____ (*supervisor@sl.on.ca*). If you have concerns about the way this research is being conducted or about your rights as a participant you may contact the SLC-REB Chair at reb@sl.on.ca .

Consent

If you agree to allow your child to take part in this research project, please complete the following form and return it to me as soon as possible. A copy of this signed document will be given to you for your own records.

By signing this form, I agree that:

- ☐ The study has been explained to me.
- ☐ All my questions were answered to my satisfaction.
- ☐ Possible harms, discomforts, and possible benefits to my child for participating in this study have been explained to me.
- ☐ I understand that my child has the right not to participate and the right to stop at any time.
- ☐ I understand that I can ask for more information about the study at any time
- ☐ I have been told that my child's personal information will be kept confidential.
- ☐ I understand that no information that can identify my child will be released or printed without my prior consent.
- ☐ I understand that I will receive a signed copy of this consent form.
- ☐ I understand that the data from this study will be presented at the St. Lawrence College Behavioural Psychology Poster Gala, and may be reported at other conferences or published in a scientific journal. No identifying information from my child will be included in these reports.

I hereby consent for my child, _____ to take part.

Parent/Guardian Name	Signature of Parent/Guardian	Date
Student Printed Name	Signature of Student	Date

Sample #3 – Child Assent Script (oral assent)

Hi. My name is [name] and I am a student at St. Lawrence College. I am doing a research project for my studies at school and I would like your help. Research projects help us learn new things. First, we ask a question. Then we try to find the answer. If you take part in my research project, you will help me learn about the possible benefits of expressive writing (about how writing about your emotions can help someone learn to understand their emotions).

You do not have to take part in this research project and no one will be upset with you if you decide you don't want to take part in it. The choice is yours: you can say "yes" or you can say "no", and you can change your mind at any time.

In this research project we will talk about writing about your emotions. If you want to take part in my research project, then this is what I would like you to do: First, I will ask you to complete a short survey. After that, we will meet twice a week on your lunch hour to do some writing and then talk about it. I will also ask you to tell me how you are feeling before and after. We will do that for 8 weeks. At the end of the 8 weeks, I will ask you to fill out another survey.

I am grateful for your help with my research project. What you get out of this is that maybe writing about your emotions will help you learn how to deal with them.

I will not identify you or anything you tell me in my research project.

If you ever have any problems and need to talk about your emotions, you can talk to

me, or your counselor [*name*]. You don't have to take part in this research project if you don't want to. If you agree to take part in it, you can change your mind at any time. If you would like to stop, just let me or [*name*] know.

Do you have any questions? Do you understand everything that I have just explained and what we will be doing together? Would you like to start?

Important: Keep a note in your research log: Write down the date, time, and the name of the child and include a statement to the effect that "I have explained the research project to the [*child's first name*] and to his/her parents. [*Name of child*] has had time to think about participating. He/she understands what the research involves. He/she has had an opportunity to ask me any questions and they consent to participate."