St. Lawrence College

REC-P Guidelines for Creating an Informed Consent Form

Research Ethics Committee- Psychology (REC-P)

ST. LAWRENCECOLLEGE

Academic Year 2022-2023

Introduction

Before commencing an intervention with a client, whether the client is a child or an adult, the student is expected to obtain consent/assent from the participants, parents or legal guardians for the thesis research project. The student may do client observations without disrupting the natural environment and complete a functional assessment (without consent), but is required to get consent before implementing an intervention. Therefore, the student is expected to create a consent form that describes in lay language the specifics of the thesis research project including data collection and interventions.

To facilitate this process, guidelines to create the consent and assent forms and templates are available to the students on the Blackboard site under the BPSYC Central. Students should customize the applicable forms to their specific project. Students are expected to discuss with agency supervisors the agency's policies around conducting research with clients and applicable regulations concerning clients' privacy and confidentiality. Students will then present a draft consent form/assent form for their agency's input before it is considered for use. The consent form must be shared with and approved by their college supervisor and a copy of the consent form (without participant identifying information) must be sent to the Research Services Office with the application form and supporting documents for REC-P ethical review. <u>It is imperative that students wait for REC-P Letter of Approval before asking clients to complete the consent form</u>. Please see the following guidelines for creating a consent form. The

student must submit the signed consent forms or an Agency Verification Letter to the college supervisor at Placement Review 2 (Week 10) or Placement Review 3 (Week 14).

When to Use Consent

All fourth-year thesis research involving human participants require a consent form. For research involving participants under the age of 18 or for any individual without the capacity to consent for themselves an assent form will also be required. Written consent is required anytime you ask someone to contribute their opinion or complete a task or when a person is identifiable in your research project and dissemination of findings. If a student is developing a training manual or is reviewing existing programs and they ask staff or clients to test out portions of the intervention and assess how it has changed their behaviour and they plan to include this information in their thesis, then consent is required.

When Consent is Not Required

Consent is not required to develop a training manual. If staff or clients just try it out to demonstrate to the student how it looks in practice and to provide feedback on whether the manual is complete, consent is not required. Feedback from staff should not be included as data in the result section of the thesis.

Informed Consent Guidelines

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. Consent is ongoing throughout a research project. 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 and benefits are if they choose to participate. It is also important for them to understand that if they choose to consent to participate that they can choose at a later time to change their mind and withdraw their original consent. Withdrawing their consent also involves a reasonable opportunity to withdraw their identifiable data as well.

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.

How to write a clear consent form:

- Use lay language (explain technical terms, acronyms, and jargon).
- Generally, use 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

Format Standards Include,
but are not limited to:

- A minimum of 12-point type size and double-spaced
- Sans serif font (such as Arial) or 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.

Required Information

- Title of the research
- Student researcher name
- Faculty supervisor name and credentials
- Name of the Institution: St. Lawrence College
- Name of Agency

Required Statements

The required elements for most consent forms include, but are not limited to:

1. **Invitation**

   A statement that the study involves research. Statements should include:

   - ☐ Invitation to participate
   - ☐ Inclusion/exclusion criteria (if applicable)
   - ☐ Identification of the student researcher
   - ☐ Identification of the sponsor (if applicable)

2. **Why is this research study being done?**

   - ☐ Statement that explains the research purpose in lay terms.

3. **What will you need to do if you take part?**

   Statements that include a descriptions of:

   - ☐ Nature, duration and frequency of research-related tasks
   - ☐ Explanation of other responsibilities of the participant
   - ☐ In the case where the consent giver is not the actual participant, this must be stated clearly and the consent giver should be informed that the

participant has an option to refuse to participate when their assent is sought

4. **What are the potential benefits of taking part?**

- Statement that identify the potential benefits to the participants (if applicable). Do not overstate the benefits
- Secondary benefits may include contributing to discipline-based knowledge or contributing to improving services at the agency

5. **What are the potential risks of taking part?**

A list of foreseeable risks, including:

- Identification of potential foreseeable risks or harms
- Explanation of measures to mitigate risks

6. **What happens if something goes wrong?**

- Explanation of process to address possibility if something goes wrong and a participant needs assistance (e.g., available counselling)

7. **Will the information you collect from me in this research be kept private?**

Provide statements describing the extent to which confidentiality will be maintained, including:

- Assurance that the participant privacy and confidentiality is important
- Explanation of measures to minimize privacy and confidentiality risks
- Statement of limits of confidentiality (e.g., “unless required by law”) if relevant
- Information about what data will be collected

- How data will have identifiers removed (e.g., de-identified, pseudonymized, anonymized) if necessary
- How data from the research will be stored and protected
- How data from the research will be destroyed, and after what time period (e.g., 6 months after the completion of the research). If there is the possibility of presenting or publishing external to SLC negotiate data retention time period with your college supervisor
- How the consent form will be stored and protected and the length of time the consent form will be kept
- How will data be reported in, for example, publications (i.e., only non-identifying, aggregate data) and where it will be presented (e.g., in thesis and BPSYC Poster Gala)

8. Do you have to take part?

Provide statements reiterating that participation is voluntary, including:

- A statement that clarifies if the individual can participate in the program/intervention if not consenting to participate in the study.
- A statement that 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). If data is identifiable, then provide a realistic amount of time for withdrawal (e.g., up to 2 weeks after completion of participation)

9. Contact for further Information:

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).

- ☐ A statement regarding obtained ethical clearance from SLC-REB
- ☐ Identification of the student researcher and the faculty supervisor contact information (email)
- ☐ SLC-REB contact information

Please note: When submitting the consent form for REC-P review, it 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 spelled out 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.

If you have any questions, please feel free to ask for assistance by emailing reb@sl.on.ca.

Sample Consent Form

Generic Consent Form – Grade 8 Reading level

Research title: 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 [*Agency*]. At the same time that I am at this placement, I am completing an applied thesis research project as part of my college program. The information in this form will help you understand my research. Please read the information carefully and ask all the questions you might have before you decide if you want to participate.

Why is this research study being done?

My project is on the Go Goddess Program – a program that aspires to help young women increase their self-esteem by helping them appreciate the value of their interests, their friends, and themselves. I have created a questionnaire to see if the group has been helpful to you. We want to know what parts of the program were most

helpful to you. Your answers will help us make this program better.

What will you need to do if you take part?

If you choose to take part in the study, you will be asked to take part in 8 sessions of the Go Goddess Program. During the sessions you will participate in interactive activities and discussion about topics related to self-esteem, values and friendship. 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 about your own self-esteem that will take about 20 minutes to complete. At the end of the program, you will be asked to complete the same questionnaire. Also at the end of each weekly session, you will be asked to fill out a 5 minutes questionnaire on your satisfaction with the session.

What are the potential benefits of taking part?

By participating in this research you might learn new ways to improve your self-esteem. Research results might help improve the Go Goddess Program for other young women in the future.

What are the potential risks of taking part?

Although risks are minimal, participating in group discussion and responding to some of the questions may make you feel uncomfortable.

What happens if something goes wrong?

If feeling uncomfortable, you may talk to your counsellor, the Go Goddess facilitator or me. If when filling out the questionnaire some of the questions make you feel uncomfortable, you can skip the question.

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

Your privacy and confidentiality are important to us. We will take every reasonable step to keep any information that identifies you confidential unless required by law. In order to protect your privacy, we will remove all information that identifies you and replace it

with either a code or fake name. Informed Consent Forms will be stored in a locked cabinet at St. Lawrence College for 10 years. All other research data will be stored securely at A*gency X* for 6 months after the completion of the research, after which time it will be destroyed. The results from the research are part of my thesis and my thesis will be made available at the St. Lawrence College library. The results will also be presented at St. Lawrence College's Behavioural Psychology Poster Gala, 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 choose whether you wish to participate in this research or not. If you agree to take part, you will be asked to sign this consent form. Even after you consent to be a participant in this research project, you may withdraw your consent at any time, without giving any reason. Choosing not to participate or withdrawing consent at a later time won't have any impact on the services you receive from [*Agency X*]. If you want to withdraw from the study, please speak to me or my supervisor. If you want to withdraw your data as well, please let me or my supervisor [*name*] know. You will be able to withdraw your data up to two (2) weeks after the study ends

Contact for further information

This research 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 [name], my supervisor from St. Lawrence College. Thank you for your consideration. If you have more questions, feel free to ask me, [student name], at [*student@sl.on.ca*]. You can also ask my college Supervisor, [name], at [*supervisor@sl.on.ca*]. If you have any worries 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 participate in this research, 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 St. Lawrence College.

By checking the following statements and signing this form, I agree that:

- ☐ I understand what the research is about and what I am being asked to do.
- ☐ Any questions I had were answered.
- ☐ Potential risks and benefits of this study have been explained to me.
- ☐ I understand that I have the right not to consent to participate.
- ☐ I understand I have the right to withdraw from the study at any time.

- ☐ I understand who I can contact if I have any questions or concerns about the research and how it is being conducted.
- ☐ I have been informed that the information I share for this research will be kept confidential.
- ☐ 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 published in the St. Lawrence College Library. No identifying information will be included in these reports or at any conferences.

I hereby consent to take part.

Participant Name	Signature of Participant	Date

Student Printed Name	Signature of Student	Date