Elements of Informed Consent

Researchers must obtain the signed informed consent of participants. For those younger than 18 years of age, the researcher must obtain the signed informed consent of parents or legal guardian, and all reasonable attempts must be made to obtain each participant's assent, which is defined as the participant's agreement to participate in the study.

The informed consent must include the following in sequential order and in language that the participants can understand:

1. Statement of purpose of the study.
2. Short description of methodology and duration of participant involvement.
3. Statement of risks/benefits to the participants.
4. Statement of data confidentiality.
5. Statement regarding the right of the participant to withdraw from the study at any time without negative consequences.
6. An offer to answer any questions the participant may have.
7. Contact information of all principal investigators, and contact information for IRB Office in the event of any adverse event or complaint.

   Lee College IRB Office
   Phone: 281.425.6455
   email: IRB@lee.edu

8. Line for signature of participants and/or parents or legal guardian except for questionnaire research, in which return of questionnaire gives implied consent.
9. Statement that participant is 18 years of age or older, unless parent or legal guardian has given consent.

In situations where participants will be deceived, items 1 and 2 are omitted and participants are told (on the signed form) that disclosure of the purpose and/or methodology could bias the outcome of the study. In this case, after the study is complete, each participant must be presented with a description of the purpose and methodology as carried out, and this document must be signed by the participants after the fact in order to guarantee informed consent.

Sample Consent

The following suggestions are offered as guidelines. The exact language is the decision of the project director/ researcher. Keep in mind, however, that the Institutional Review Board must determine if the participants will be giving informed consent. (Note: that in the case of children, assent is also required).

Dear (student, parent, sir, madam, etc.):

We are conducting a study to determine _____. In this study, you (your child/ward) will be asked to _____. Your participation should take about _____ minutes.

AND

There are no risks to you (your child/ward).

or

Risks to you (your child/ward) include _____.

All information will be handled in a strictly confidential manner, so that no one will be able to identify you (your child/ward) when the results are recorded/reported.

Your (child's/ward's) participation in this project/study is totally voluntary and you may withdraw at any time without negative consequences. If you wish to withdraw at any time during the study, simply _____.

Please feel free to contact _____ (**names(s), title(s) of principal researchers**) at _____ if you have any questions about the study. To report any adverse events, complaints or concerns about this study please contact the IRB office by e-mail at IRB@lee.edu or by phone at 281-425-6455.

NOTE- If the participant is of age (18 years old or older), use the following:

I understand the study described above and have been given a copy of the description as outlined above. I am 18 years of age or older and I agree to participate.

_____ _____

Signature of Participant Date

NOTE: If the participant is not of age, use the ASSENT format:

I understand the study described above and have been given a copy of the description as outlined above. I agree to allow my child/ward to participate with his/her assent when possible.

Signature of Participant Parent or Guardian	Date

I understand what I must do in this study, and I want to take part in the study.

Signature of Participant	Date

Informed Consent Checklist

Lee College System

Institutional Review Board

This form is to be completed by the CRRC and/or the IRB in their review of the informed consent process for this project.

Project Name: _____

Primary Investigator: _____

Date of this review: _____

		YES	NO	N/A
1	Is the consent form written in lay language?			
2.	Is the consent form free of language that requires the subjects to waive their legal rights, including any release of the investigator, sponsor, or college or its agents from liability for negligence?			
3.	If minors are included in the study, have provisions been made to obtain parental consent?			
4.	Does the consent form include each of the following basic elements of informed consent?			
4	a. A statement that the study involved research, an explanation of the purposes of the research and the expected duration of the subject's participation.			
	b. A description of the procedures to be followed.			
	c. A description of any benefits to the subject or others.			
	d. A description of any reasonably foreseeable risks or discomforts.			
	e. A statement describing the extent to which confidentiality of records identifying the participant will be maintained.			
	f. Information regarding whom to contact for answers to questions about the research study and the research subject's rights.			
	g. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits, and the participant may discontinue participation at any time without penalty or loss of benefits.			
	h. FERPA notice and waivers (if appropriate).			