**Guide to the Preparation of Letters of Informed Consent**

**1. Title:** Descriptive title.

**2. Principal Investigator:** Include name of Principal Investigator and other researchers as appropriate with their contactinformation and institutional or program affiliations. This includes the faculty principal investigators supervising research carried out by students (including doctoral and masters).

**3. Sponsor:** If the study is funded, include the sponsor's name.

**4. Description and Purpose**: (Required in all consent forms). May be one or more sections; modify heading(s) as appropriate.

This part of the consent form must include:

* A statement that potential subjects are being asked to volunteer for a research study;
* An explanation of why the subject is being asked to volunteer;
* A clear explanation of the purpose of the research;
* The expected duration of the subject's totalparticipation;
* The approximate number ofsubjects to be enrolled in the study at Lesley University and elsewhere. (This information is only required when the number of subjects is material to the person's decision to participate; e.g., small sample size might compromise anonymity.)

**5. Procedures:** (Required in all consent forms)

a) A description and explanation of the procedures that will be performed on the subject, e.g., filling out questionnaires, being interviewed, being audio or videotaped, engaging in role-playing or performing computerized experiments.

b) A full explanation of all responsibilities and expectations of the subject. Be sure to communicate the following:

* All of the different people with whom the subject will interact.
* Where the research will be done.
* When the research will be done.
* How often the procedures will be performed.
* How much of the subject's time will be involved in each session and the number of sessions.

**6. Risks:** (Required in all consent forms)

a) A description of any possible discomforts or **risks** that may exist. Explain how **anonymity** will be assured if that is a potential problem. Explain what will happen to data collected, including any video or audio recordings, once the study is completed.

This section should include a statement thatthe research may not provide any benefit to the subject. Any benefits to the subject or others that can be expected should be described in a way that is not coercive, enticing, or self-serving. Benefit to society is appropriate. Do not refer to financial compensation in this section. The following is acceptable wording for this section:

*Participation in research is voluntary. You have the right to refuse to be in this study. If you decide to be in the study and change your mind, you have the right drop out at any time. You may skip questions. Whatever you decide, you will not lose any benefits to which you are otherwise entitled*.

b) If your study does involve any risk of physical harm to subjects, the following statement shall be included on the consent form:

*If you are injured during the course of the study and as a direct result of this study, you should contact the investigator at the number**or e-mail address provided. Although compensation is not available, Lesley University will assist you in obtaining medical treatment, including first aid, emergency treatment, and follow-up care as needed. Your insurance carrier should be billed for the cost of such treatment. If your insurance carrier denies coverage, Lesley University is under no obligation to pay for the treatment but may do so at its discretion. By providing financial or other assistance, neither Lesley University nor the researchers are stating that they are legally responsible for the injury.*

**7. Confidentiality, Privacy and Anonymity:** (Required in all consent forms)

The following is acceptable wording for this statement, but this wording can be modified as appropriate:

*You have the right to remain anonymous. If you elect to remain anonymous, we will keep your records private and confidential* ***to the extent allowed by law****. We will use numerical identifiers rather than your name on study records. Your name and other facts that might identify you will not appear when we present this study or publish its results.*

*If for some reason you do not wish to remain anonymous, you may specifically authorize the use of material that would identify you as a subject in the research.*

The consent form should end with statements similar to the following:

*We will give you a copy of this consent form to keep.*

Both the investigator and the subject should keep a copy of the signed form.

**We require that you add this exact paragraph at the bottom of the form:**

*There is a Standing Committee for Human Subjects in Research at Lesley University to which complaints or problems concerning any research project may, and should, be reported if they arise. Contact the Committee Chairperson at* *irb@lesley.edu**.*

 **8. Signatures and names:** (Required in all consent forms)

a) **Investigator's Signature**:

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Date Investigator's Signature Print Name

b) **Subject's Signature**:

*I am 18**years of age or older.**The nature and purpose of this research have been satisfactorily explained to me and I agree to become a participant in the study as described above. I understand that I am free to discontinue participation at any time if I so choose, and that the investigator will gladly answer any questions that arise during the course of the research.*

\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date Subject's Signature Print Name

**If needed:**

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Date Signature of Parent/Guardian or Print Name

 Legally Authorized Representative

 (This line is required only if the subject is not able to consent for herself or himself).