Youngstown State University

ELEMENTS OF INFORMED CONSENT

Researchers must obtain the ***informed consent*** of participants. For those less than 18 years of age, the researcher must obtain the 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 which 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. Name, title, address, and phone number of all principal investigators.

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 I 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 INFORMED CONSENT

The exact language of the consent document is the decision of the researcher but your document must fully inform participants and contain all elements of consent pertinent to your research. If you use the template below remove all colored typing, and check for grammar/sentence structure and spelling errors so that the final document reads easily. Check to be sure that nothing important is left out because a template cannot meet requirements for all projects. (Note: that in the case of children, parents give "consent" and children give "assent" – see the signature areas at the end of the template for details.).

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

I am/We are [identify yourself as a faculty, student or staff] from Youngstown State University. I am/We are conducting a study to investigate _____. In this study, you (your child) will be asked to ___[list in order of sequence what the person will do and/or what will be done to him/her]___. I /We will also need to collect information to describe you such as __[age, race, grade level, etc. If you will access any private records to get information about the person (educational/student record, health record, employee record), you must inform participants WHO will go into the private record to get the data and identify ALL information to be collected out of the record] _____. You will meet with me/us for ____ sessions and your participation should take about _____ minutes each time.

You (your child) may be at risk of harm because of this research. The harm include/s: :_____. [The harm types are physical, emotional/psychological, societal and economic as well as a breach of privacy. You should determine all the types of risk your project poses and then give specifics, not just list the type. For example: 1) The survey you will complete asks about …….and you may have negative emotional feelings when completing the survey. 2) When you perform the tests in this study, you may get muscle soreness. 3) You may become embarrassed if a breach of confidentiality allowed your business practices to become known in the community.] The likelihood that you will be harmed is minimized because I/we will_____ .

The benefits to you from being in this study are _____. [if there are no direct benefits to the participant, you can list benefits to society instead.]

Your privacy is important and I/we will handle all information collected about you in a confidential manner. I/We will report the results of the project in a way that will not identify you (your child). I/We do plan to present the results of the study to/at _____

You do not have to be in this study. If you don't want to, you can say no without losing any benefits that you are entitled to. If you do agree, you can stop participating at any time. If you wish to withdraw just tell me or the contact person listed below.

If you have questions about this research project please contact [insert here the principal investigator's/faculty advisor's name and contact information]. If you have questions about your rights as a participant in a research project, you may contact the Office of Research Services at YSU (330-941-2377) or at YSUIRB@ysu.edu

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

I understand the study described above and have been given a copy of this consent document. I am 18 years of age or older and I agree to participate.

_____

Signature of Participant Date

If the participant is not of age, obtain parental consent by using:

I understand the study described above and have been given a copy of this consent document. I agree to allow my child to participate with his/her assent.

_____

Signature of Parent/Guardian Date

If the participant is a minor (less than 18 years old), use the parental consent above and include this ASSENT format:

I understand what I must do in this study and I want to do it.

_____

Signature of Child Date