Tyler Junior College
Institutional Review Board

ELEMENTS OF INFORMED CONSENT

Researchers must obtain the signed ***informed consent*** of participants. For those less 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 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. Explanation of compensation, where applicable.

5. Statement of data confidentiality.

6. Statement regarding the right of the participant to withdraw from the study at any time without negative consequences.

7. An offer to answer any questions the participant may have.

8. Contact information of all Principal Investigators, as well as contact information for Tyler Junior College's Institutional Review Board (currently Dr. Afton Barber, IRB Chair, 903.510.2305).

9. Statement of approval by the Tyler Junior College Institutional Review Board.

10. Line for signature of participant, including a statement that the person is of age; or line for signature of both parents or legal guardian(s) of underage participant (except for questionnaire research in which return of questionnaire gives implied consent). (See Administrative Procedures, Special Considerations, Section A, for specific information regarding required parents signatures).

11. Where applicable, a signature line for assent of a participant under 18.

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.

Include with your review application the actual Consent Form that will be provided to the participants.

Tyler Junior College

SAMPLE INFORMED CONSENT

The following suggestions are offered as guidelines. The exact language is the decision of the 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, it is ***assent***).

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

We are/I am conducting a study to determine_____. In this study, you (your child/ward) will be asked to_____. Your participation should take about_____(length of time – minutes, hours, weeks, etc.)

There are no risks to you (your child/ward) ***or*** The only risks to you are _____

Benefits to participation are (include statement if applicable) _____

You (your child/ward) will be compensated_____(include only if applicable).

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 (your child's/ward's) participation in this 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_____phone) if you have any questions about the study. Or, for other questions, contact the IRB Chair (903.510.2305).

This research has been approved by the Institutional Review Board of Tyler Junior College.
Protocol #_____ Date_____

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

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

OR *If the participant is not of age:*

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. (both parents must sign)

_____ _____
Signature of Parent/Guardian Date Signature of Parent/Guardian Date

And *ASSENT format:*

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

_____
Signature of Child/Ward Date