

### 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. 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 also contact information for Columbia State's Institutional Review Board (Director of Institutional Effectiveness).
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.

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**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, 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.

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

*or*

The only 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 (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 Sinclair's Director of Research, Analytics, and Reporting (937-512-2558).

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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 the description as outlined above. I am 18 years of age or older and I agree to participate.

\_\_\_\_\_  
Signature of Participant

\_\_\_\_\_  
Date

*If the participant is not of age, use:*

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 Parent/Guardian

\_\_\_\_\_  
Date

*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