Trinity Valley Community 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 Trinity Valley Community College's Institutional Review Board (currently Tina Tummel, Director, Institutional Research, 903.675.6282 or trummel@tvcc.edu).
- 9. Statement of approval by the Trinity Valley Community 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.

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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, parents, sir, madam, etc.):		
We are/I am conducting a study to determine	In th	is study, you
(your child/ward) will be asked to	Your pa	rticipation 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	t if applicable)	
You (your child/ward) will be compensated _	(include only	if applicable).
All information will be handled in a strictly condentify you (your child/ward) when the result		will be able to
Your (your child's/ward's) participation in this any time without negative consequences. If y simply	ou wish to withdraw at any time du	•
Please feel free to contact at phone) if you have any questio Tina Tummel, Director, Institutional Research This research has been approved by the Institution College.	ns about the study. Or, for other qua, 903.675.6282 or trummel@tvcc.	edu.
Protocol #	Date	
If the participant is of age (18 years old or older): I understand the study described above and ha above. I am 18 years of age or older and I agree		ption as outlined
	Signature of Participant	Date
OR If the participant is not of age: I understand the study described above and ha outlined above. I agree to allow my child/ware	we been given a copy of the descri	
Signature of Parent/Guardian Date And ASSENT format: I understand what I must do in this study and	Signature of Parent/Guardian I want to take part in the study.	Date
·	Signature of Child/Ward	Date