Required Elements for Informed Consent

A. Authorization

Example:

I, _____(respondent)_____, hereby authorize or direct _____(researcher)_____, or associates or assistants of his or her choosing, to perform the following treatment or procedure.

B. Description of Research and Associated Risks/Benefits

The researcher must include the following elements in his/her description of the procedure:

1. Name of research project.
2. Statement that the study involved research and is being conducted through Jamestown College, and name(s) of PIs and their relationship with JC.
3. Explanation of the purposes of the research and the expected duration of the participant's participation
4. Description of the procedures to be utilized
5. Description of any reasonably foreseeable risks or discomfort to the participant
6. Description of any benefits to the participant or to others that reasonably may be expected from the research
7. Statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained. Remember not to guarantee confidentiality, but to ensure protection and describe how this protection of confidentiality will be carried out.
8. For research involving more than minimal risk, an explanation about
   - ✓ Whether any compensation is available if injury occurs
   - ✓ Whether any medical treatments or other support services are available if injury occurs
   - ✓ If such treatments are available, what they consist of and where further information can be obtained
9. Explanation of how and whom to contact about:
   - ✓ The research (the PI)
   - ✓ Research participants' rights (the IRB Chair)
   - ✓ Research-related injury to the participant

NOTE: The elements listed above are required components of the consent process whether informed consent is obtained in a written form or not. It is imperative that the consent procedures be stated at the level appropriate to the participants.

C. Voluntary Participation

Example:

I understand that participation is voluntary and that I will not be penalized if I choose not to participate. I also understand that I am free to withdraw my consent and end my participation in the project at any time without penalty after I notify the project director. (NOTE: the name of the PI and way to contact him or her or project director must be clearly stated.)

D. Consent Documentation for Written Informed Consent

Example:

I have read and fully understand the consent form. I sign it freely and voluntarily.

Name: _____ _____
Please print legibly Signature

Date: _____ Time: _____ (a.m./p.m.)

Witness's Name: _____ _____
Please print legibly Signature

I certify that I have personally explained all elements of this form to the participant or his/her representative before requesting the participant or his/her representative to sign it.

Signed: _____ Date: _____ Time: _____ (a.m./p.m.)
Project director or authorized representative