

Pittsburg State University
Committee for the Protection of Human Research Subjects
(CPHRS)

INFORMED CONSENT INSTRUCTIONS – Research Using Human Subjects

When performing research involving human subjects, it is your responsibility to address the issue of informed consent. It is a critical component of human subjects research. The purpose of informed consent is to ensure that any potential subject knows exactly what the project that you are planning is about, and what his/her potential role is. (It may at times be necessary to use forms of “deception” of the subject in order to execute the study, but these cases must be carefully justified and approved by the CPHRS.)

These instructions and the suggested template (Form IC – 2) are provided to guide you in creating an informed consent document. The Committee for Protection of Human Research Subjects (CPHRS) strongly recommends you model your consent form based on the suggested template. At a minimum, your consent form must contain the same elements as the suggested template. Language and terminology used in the consent form must be written at no more than the 8th grade level, so that the potential subject can clearly understand the project, how it is going to be conducted, and all issues that may affect his or her participation.

Further information regarding informed consent can be found in Federal Policy, Title 45, Part 46.116, Code of Federal Regulations, at <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>.

Federal law mandates that all signed and dated informed consent forms be retained by the Principal Investigator (PI) for at least three years following completion of the study.

Please answer the following questions about your informed consent procedures:

- | Yes | No | |
|------------|-----------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| ___ | ___ | a. Are you using a written informed consent form (Form IC – 2)? If yes, include a copy with your application. |
| ___ | ___ | b. In accordance with guidance in 45 CFR 46, and Form IC – 5 (Waiver of Informed Consent Instructions), I am requesting a waiver or alteration of informed consent. If yes, include a copy of your application for waiver of informed consent (Form IC – 3). |
| ___ | ___ | c. Are your research subjects anonymous? If they are anonymous, you will not have access to any information that will allow you to determine the identity of the research subjects in your study, or to link research data to a specific individual in any way. Anonymity is a powerful protection for potential research subjects. (An anonymous subject is one whose identity is unknown even to the researcher, or the data or information collected cannot be linked in any way to a specific person.) |
| ___ | ___ | d. Does your project use deception of the subjects or is it necessary for you to deceive the subjects about the full procedure and purpose of your research when obtaining their consent to participate? If yes, you must provide justification below. |

Please sign below to acknowledge that you have read the above instructions regarding informed consent and recognize your responsibility to fully address this issue in your research:

Investigator Signature

Date