Pittsburg State University

Committee for the Protection of Human Research Subjects
(CPHRS)

WAIVER OF INFORMED CONSENT INSTRUCTIONS – Research Using Human Subjects

WAIVER OF INFORMED CONSENT

There are limited instances where the requirement for a formal informed consent document may be waived or altered by the CPHRS. Guidance for when informed consent may be waived is as follows (in accordance with 45 CFR 46.116(c)(d)):

"An IRB (for PSU, the CPHRS) may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

(Section c)

(1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:
    a. Public benefit or service programs
    b. Procedures for obtaining benefits or services under those programs
    c. Possible changes in or alternatives to those programs or procedures
    d. Possible changes in methods or levels of payment for benefits or services under those programs
(2) The research could not practicably be carried out without the waiver or alteration

(Section d)

(1) The research involves no more than minimal risk to the subjects
(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects
(3) The research could not practicably be carried out without the waiver or alteration
(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation."

Further waiver guidance under 45 CFR 46.117(c) states:

"An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

(1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or
(2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context."

Requests for a waiver from obtaining informed consent must be approved by the Departmental Chair with final approval from the CPHRS. Waiver requests should be made with the initial application procedure using Form IC – 4.