STANDARD OPERATING PROCEDURE

DEPARTMENT: Institutional Review Board Administration
REFERENCE NUMBER: # 24
ORIGINAL PUBLICATION DATE: April 3, 2006
REVISION DATES: 1-5-09

Subject: Waiver or Alteration of Informed Consent

based on federal regulations, in some instances the IRB has authority to waive or alter the requirement to obtain informed consent (including the requirement to have participants sign a consent form) from subjects. The federal regulations provide specific criteria that the IRB must consider before making a decision to waive or alter either informed consent or documentation of informed consent.

The IRB may approve a consent procedure which does not include, or alters some or all of the elements of informed consent or waives the requirement to obtain informed consent provided the IRB finds and documents that:

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:

    - Public benefit or service programs;
    - Procedures for obtaining benefits or services under those programs;
    - Possible change in or alternative to those programs or procedures; or possible changes in methods or levels of payment for benefits or services under those programs;
    - The research could not practicably be carried out without the waiver or alteration; and
    - The research is not subject to FDA regulation.

2) Or the IRB finds and documents that:

    - The research is not subject to FDA regulation; and
    - The research involves no more than minimal risk to the participants; and
    - The waiver or alteration will not adversely affect the rights and welfare of the participants; and

- The research could not practicably be carried out without the waiver or alteration; and

- Whenever appropriate, the participants will be provided with additional pertinent information after participation.

Investigator Responsibilities

a. The Investigator will assess the proposed research to determine if it meets regulatory requirements for a waiver or alteration of informed consent.

b. The Investigator will address the five points above (No. 2) in the IRB application/Description of Study.

IRB Responsibilities

a. The IRB will consider the request for a wavier or alteration of informed consent and the Investigator's justification, verifying and documenting that regulatory conditions allow the proposed research activity as presented.

b. If the IRB agrees with the Investigator's justification, the Committee meeting discussion and decision, and the approval is documented in the meeting minutes and/or IRB Reviewer's Comment Form and the Principal Investigator is notified accordingly.

c. If the IRB does not agree that waiver or alteration of the consent process is allowable or appropriate under applicable regulations, the IRB Administration will inform the PI and document such decision in the minutes and/or IRB Reviewer's Comment Form.

d. When amendments are made to a currently approved research study, waiver or alteration of informed consent is reassessed by the IRB Committee, Chairperson or Chair's designee, and a determination made as to whether the conditions for the waiver or alteration have been altered, necessitating the rescinding of the waiver/alteration. If such a decision is made, the IRB will determine whether currently enrolled participants must be re-consented by the Investigator.

References:

45 CFR §46.116(c)
45 CFR §46.116(d)
45 CFR §46.117(c)(1)
Institutional Review Board Management and Function, Jones & Bartlett Publishers