

Approved by IRB Executive Committee: April 2, 2008
Supersedes Document Dated: December 12, 2005; May 1, 2004
AAHRPP Element II.7.E.

POLICY

The IRB may approve a consent procedure that does not include, or which alters, some or all of the elements (see SOP 701) if the IRB finds that the research meets specific criteria. Research involving deception requires a waiver or alteration of the consent process. **Please note that this policy does not describe the waiver of informed consent for planned emergency research or exceptions from informed consent (see SOP 502).**

PROCEDURES

1. Procedures for the Waiver or Alteration of One or More Requirement(s) of Informed Consent

- 1.1. The IRB may approve a consent procedure that does not include, or which alters, some or all of the elements of informed consent provided the research is not subject to FDA regulations and the IRB finds and documents that:
 - 1.1.1. The research involves no more than minimal risk to participants;
 - 1.1.2. The waiver or alteration will not adversely affect the rights and welfare of the participants;
 - 1.1.3. The research could not practicably be carried out without the waiver of alteration; and
 - 1.1.4. Whenever appropriate, the participants will be provided with additional pertinent information after participation.

- 1.2. The IRB may approve a consent procedure that does not include, or which alters, some or all of the elements of informed consent provided the research or demonstration project is not subject to FDA regulations and 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:
 - 1.2.1. Public benefit or service programs;
 - 1.2.2. Procedures for obtaining benefits or services under those programs;
 - 1.2.3. Possible changes in or alternatives to those programs or procedures; or possible changes in methods or levels of payment for benefits or services under those programs;

- 1.3. If the investigator wishes to waive or alter some or all of the elements of informed consent, the investigator completes the appropriate section of the IRB application within the ERICA system. The Investigator provides protocol-specific justification for waiver or alteration of consent using criteria referenced above.

- 1.4. The convened IRB or a designated IRB reviewer using the expedited procedure reviews this information and concurs or requires changes and/or

clarification before final approval. The IRB or designated IRB reviewer uses the appropriate Reviewer Checklist to determine and document whether the waiver can be granted.

- 1.5. Research which involves deception, or is designed in such a way that providing complete information during the consent process will invalidate the study, requires an informed consent document and a request for a Waiver of Alteration of Informed Consent. The investigator must complete the appropriate section of the IRB application within the ERICA system and must meet the criteria for waiver or alteration of informed consent as described in this policy.
- 1.6. In addition to the requirements outlined in this policy, if the IRB determines that a research protocol is designed for conditions or for a participant population for which parental or guardian permission is not a reasonable requirement to protect the participants (i.e. neglected or abused children), it may waive the consent requirements, provided an appropriate mechanism for protecting the children who will participate as participants in the research is substituted, and provided that the waiver is not inconsistent with Federal, state, or local law. The IRB may not waive consent requirements for parental or guardian permission if the research is subject to FDA regulations.
 - 1.6.1. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research participants, and their age, maturity, status and condition.