

Approved by IRB Executive Committee: April 8, 2009
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AAHRPP Elements: II.4.C, II.7.B

POLICY

The inclusion of certain groups of participants who may be vulnerable to undue influence or coercion may require additional protections. When the IRB reviews research involving vulnerable populations, the IRB applies any additional federal regulations, VA requirements, state and local laws, as applicable. The IRB evaluates whether additional safeguards have been included in the study to protect the rights and welfare of participants who may be vulnerable to undue influence. The IRB requires at least one or more individuals who are knowledgeable about or have experience in working with these participants are part of the review process.

New study submissions including prisoners as potential research participants are reviewed by the convened IRB and cannot be reviewed under expedited procedures. Subsequent review of amendment and continuing review applications involving prisoners may also be reviewed by a convened board. Expedited review procedures may be allowed, where the expedited reviewer is an IRB member who is a designated prisoner representative. New study submissions, amendment and continuing review applications involving other vulnerable populations may be reviewed by the convened board or by expedited review.

The IRB reviews research involving vulnerable populations according to applicable requirements and guidelines and makes determinations using the IRB reviewer checklist. If the research includes a vulnerable population that does not have additional protections specified in the federal regulations, the board will evaluate the research proposal to ensure that precautions are taken to protect the participants.

The IRB adheres to the vulnerable population guidelines posted on the IRB website (see Investigator Guidance Series on Prisoners, Children, Wards of State, Pregnant Women, Fetuses and Neonates, and Individuals with Decisional Impairment).