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Subject: Important IRB Memo
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Bulletin Topic: Committee for the Protection of Human Subjects
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To: Researchers
From: IRB Office
Topic: Research which may enroll prisoners

The IRB office has received several inquiries over the past few months related to the allowability of enrolling prisoners into a research study.

SHORT ANSWER: ANY research that may enroll prisoners at the outset of the study OR at any time during the course of the study must have PRIOR IRB approval.

BACKGROUND: Federal regulations include a section referred to as Subpart C: Additional DHHS Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects. This subpart was added to the regulations in response to research being conducted at prisons in which concerns were raised including the coercive nature of the environment. The regulations extend to research not solely being conducted at a prison but also research which may enroll a prisoner as a research subject outside the prison setting.

TO DO :

If you have enrolled a prisoner into a research project without obtaining prior IRB approval please contact our office immediately.

If you have a project in which there is a HIGH likelihood that you may enroll a prisoner and the submission to the IRB did not indicate so -- please contact the IRB to obtain approval to enroll prisoners.

ADDITIONAL INFORMATION :

In May 2003 the federal oversight agency OHRP provided guidance on this topic which may be found at: <http://ohrp.osophs.dhhs.gov/humansubjects/guidance/prisoner.htm>