

**Impact of recent OHRP Guidance on
Research Involving Prisoners**
revised 02/04 for additional OHRP certification requirements

Based upon OHRP's revised requirements for research involving prisoners, the following duties are to be carried out by the IRB and the Institution.

IRB Duties

Institutional & Misc. Duties

<p>1. IRB must document that the research represents one of the 4 categories of permissible research under 45 CFR 46.306(a)(2)</p> <ul style="list-style-type: none"> • (A) <i>study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;</i> • (B) <i>study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;</i> • (C) <i>research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults) provided that the study may proceed only after the Secretary has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of his intent to approve such research; or</i> • (D) <i>research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of the</i> 	<p>1. The Institution must certify that the IRB has reviewed and approved the research under one of the 4 categories of research permissible for the involvement of prisoners. The findings are then to be forwarded to OHRP, after which OHRP will determine if the research falls within the categories of allowable conduct of research involving prisoners. This letter is to specifically identify the research and any grants associated with the project. HHS conducted or supported research may not commence until OHRP has made its determination regarding the research. Note: this only applies to research conducted or supported by DHHS.</p>
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	<i>intent to approve such research.</i>		
2.	Documenting that any possible advantages accrued to the prisoner through their participation in the research does not impair their ability to weigh the risks/benefits of the participation in the limited choice environment that exists at a prison.	2.	The Institution must certify to OHRP that the 7 duties described in the left column have been completed and documented (“OHRP would consider documentation of protocol-specific information justifying each IRB finding under the regulations to be one way of adequately documenting the IRB activities required under Subpart C”); and provide a reasonably detailed description of the research.
3.	Documenting that the risks of the research are commensurate with those that would be accepted by non-prisoners.	3.	The IRB must have on record the CV of the prisoner representative serving on the Board.
4.	Documenting that selection of prisoner research participants are fair and equitable and immune from arbitrary intervention by prisoner authorities; unless the PI provides justification for an alternative procedure.		
5.	Documenting that the information presented to the prisoners is done so in a language understandable by the participant.		
6.	Documenting that adequate assurance is in place that parole boards will not take into account participation in the research when determining parole, and that the prisoners were clearly informed of this measure.		
7.	Documenting that in cases where follow-up or care is required after the end of participation, that adequate measures have been taken to provide that care (taking into account the length of the prisoners’ sentences).		
A	The definition of minimal risk for prisoner research differs from the Common Rule definition in the following way: 1) harm pertains to physical or psychological elements of a prisoner’s life and the research; 2) normal and healthy persons (who are non prisoners) must be the normative standard for ethical evaluation of the research – not conditions inherent in a penal system.		
C	Control groups involving prisoners that may not receive direct benefit from the research must automatically be forwarded to OHRP for review by a panel of experts and seek comment through placement in the Federal Register.		

Items above are referenced (and often taken verbatim) from 45 CFR 46 Subpart C; the Amdur & Bankert text; and OHRP’s IRB Guidebook that is available on-line at OHRP’s web site.