

Reviewer:

PRO #

PI:

This checklist must be completed by an IRB member with sufficient expertise. In order to approve the use of prisoners, responses must be “yes” unless not applicable:			
		Yes	No
1.	The research falls under one of the 5 categories of section 306(a)(2),	Yes	No
1.	Study of the possible causes, effects and process of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;		
2.	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;		
3.	Research on conditions particularly affecting prisoners as a class; For DHHS-funded research, OHRP has consulted with appropriate experts in penology, medicine, and ethics, and published notice in the Federal Register of its intent to approve such research;		
4.	Research on practices, both innovative and accepted, which have the Intent and reasonable probability of improving the health or well-being of the subject. For DHHS-funded research which 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 OHRP has consulted with appropriate experts, including experts in penology, medicine, and ethics and published notice in the Federal Register of its intent to approve such research;		
5.	Epidemiologic studies which meet the following criteria:		
a.	The sole purposes are one of the following:		
i.	To describe the prevalence or incidence of a disease by identifying all cases or		
ii.	To study potential risk factor associations for a disease.		
b.	The research presents no more than minimal risk and no more than inconvenience to the prisoner-subjects, and		
c.	Prisoners are not a particular focus of the research.		
1	Advantages are not coercive to prisoners	Yes	No
2	Risks are commensurate with risks that would be accepted by non-prisoner volunteers	Yes	No
3	Selection of subjects is fair and immune from prison intervention. Unless the Principal Investigator provides justification in writing for following some other procedures, control participants are selected randomly from the group of available prisoners who meet the characteristics needed for that particular study	Yes	No
4	Information must be presented in language which is understandable to the subjects;	Yes	No
5	Parole boards will not take prisoner participation in research into consideration when they make parole decisions and each prisoner is clearly informed in advance that participation in the study will have no effect on their parole;	Yes	No
6	Adequate provisions are made if follow-up is needed.	Yes	No
7	For DHHS-funded research, the organization certifies to OHRP the duties of the IRB have been fulfilled.	Yes	No
8	If research is DoD funded, the DoD Requirements have been met.	N/A	Yes No