



**REVIEWER CHECKLIST
PRISONERS AS SUBJECTS IN RESEARCH**

REQUIRED CATEGORIES: *Please indicate which category applies to this study. One of the following categories must apply in order for the research to be approvable.*

Category A:

This study involves the possible causes, effects, and processes of incarceration, and of criminal behavior and this study presents no more than minimal risk and no more than inconvenience to the participants.

Category B:

This is a study of prisons as institutional structures or of prisoners as incarcerated persons and this study presents no more than minimal risk and no more than inconvenience to the subjects.

Category C:

Prisoners are not a particular focus of the research and this study presents no more than minimal risk and no more than inconvenience to the subjects and the sole purposes of the research are one or more of the following:

- To describe the prevalence or incidence of a disease by identifying all cases **OR**
- To study potential risk factor associations for disease

Category D:

This is research on conditions particularly affecting prisoners as a class (e.g., research on hepatitis which is more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults) and the research is conducted or supported by DHHS and the Secretary has consulted with appropriate experts including experts in penology, medicine, and ethics and the Secretary has published notice, in the Federal Register, of his intent to approve such research.

Category E:

The research is on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject and one of the following is true:

- The research does not require the assignment of prisoners to control groups that may not benefit from the research **OR**
- The research is conducted or supported by DHHS and the Secretary has consulted with appropriate experts including experts in penology, medicine, and ethics and the Secretary has published notice, in the Federal Register, of his intent to approve such research.

Clear

OTHER NECESSARY CONSIDERATIONS:

Please indicate the sections that apply to this study. All of the following must be "true" for the research to be approvable. If you answer "False", describe in Requested Revisions/Clarifications section.

<p>True False Clear</p>	<p>One of the following is true:</p> <p>Any possible disadvantages accruing to the prisoner through his/her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his/her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired OR</p> <p>The research under review represents "Category C" above.</p>
<p>True False Clear</p>	<p>The risks involved in this research are commensurate with risks that would be accepted by non-prisoner volunteers;</p>
	<p>Procedures for the selection of subjects within the prison are fair to all prisoners and immune</p>

True	False	Clear	from arbitrary intervention by prison authorities or prisoners.
True	False	Clear	<p>One of the following is true:</p> <p>Control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project OR</p> <p>The principal investigator has provided justification to the IRB for following other procedures.</p>
True	False	Clear	The information is presented in language which is understandable to the subject population.
True	False	Clear	Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole.
True	False	Clear	Each prisoner is clearly informed in advance that participation in the research will have no effect on his/her parole; and
True	False	Clear	Where the IRB finds there may be a need for follow-up examination or care of participation after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths or individual prisoners' sentences, and for informing participants of this fact.
True	False	Clear	<p>One of the following is true:</p> <p>The research is NOT conducted or supported by DHHS OR</p> <p>The institution responsible for the conduct of the research has certified to the Secretary that the Institutional Review Board has approved the research and in the judgment of the Secretary the proposed research involves solely one of the permissible categories.</p>

Determination of Research Involving Prisoners:

The proposed involvement of prisoners is Approvable.

The proposed involvement of prisoners cannot be determined at this time and needs further clarification noted below.

The proposed involvement of prisoners is Not Approvable.

Clear

Requested Revisions/Clarifications: Provide more information if you answered "False" to any statements above or if you are unable to make a determination.