

CHECKLIST: Prisoners

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This checklist is used to determine and document whether non-exempt <Human Research> involving <Prisoners> can be approved.

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All criteria in 1 must be met

1. Research involving <Prisoners> as subjects *45 CFR §46 Subpart C (see Footnote 1)*

1.1	<input type="checkbox"/>	The research under review represents one or more of the categories: (Select at least 1)	
	Cat 1	<input type="checkbox"/>	The research involves the study of the possible causes, effects, and processes of incarceration, and of criminal behavior that present no more than <Minimal Risk> (see Footnote 2) and no more than inconvenience to the subjects
	Cat 2	<input type="checkbox"/>	The research involves the study of prisons as institutional structures or of <Prisoners> as incarcerated persons that present no more than <Minimal Risk> (see Footnote 2) and no more than inconvenience to the subjects
	Cat 3	<input type="checkbox"/>	All of the following are true:
		Cat 3.1	<input type="checkbox"/> The research is on conditions particularly affecting <Prisoners> as a class (see Footnote 3)
		Cat 3.2	<input type="checkbox"/> One of the following is true: <input type="radio"/> The research is not subject to DHS, EPA, or VA regulation and is not HHS-funded <input type="radio"/> The study will not proceed until an applicable official has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of the intent to approve such research (see Footnote 4)
	Cat 4	<input type="checkbox"/>	All of the following are true:
		Cat 4.1	<input type="checkbox"/> 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
		Cat 4.2	<input type="checkbox"/> One of the following is true: <input type="radio"/> The research is not subject to DHS, EPA, or VA regulation and is not HHS-funded <input type="radio"/> The research does not require assignment of <Prisoners> to control groups that may not benefit from the research (see Footnote 5) <input type="radio"/> The study will not proceed until an applicable official has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of the intent to approve such research (see Footnote 4)
	Cat 5	<input type="checkbox"/>	Epidemiologic studies where prisoners are not a particular focus of the research in which the sole purposes are to describe the prevalence or incidence of a disease by identifying all cases, or to study potential risk factor associations for a disease, and the study presents no more than <Minimal Risk> (see Footnote 2) and no more than inconvenience to <Prisoners> who are subjects

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1.2	<input type="checkbox"/>	Any possible advantages accruing to the <Prisoner> through his or 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 or 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
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1.3	<input type="checkbox"/>	The risks involved in the research are commensurate with risks that would be accepted by non-<Prisoner> volunteers
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1.4	<input type="checkbox"/>	Procedures for the selection of subjects within the prison are fair to all <Prisoners> and immune from arbitrary intervention by prison authorities or <Prisoners>
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1.5	<input type="checkbox"/>	One of the following is true: <input type="radio"/> Control subjects will be selected randomly from the available <Prisoners> who meet the characteristics needed for the research <input type="radio"/> The principal investigator has provided written justification for following other procedures
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1.6	<input type="checkbox"/>	The information is presented in language which is understandable to the subject population
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1.7	<input type="checkbox"/>	Adequate assurance exists that parole boards will not take into account a <Prisoner>'s participation in the research in making decisions regarding parole
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1.8	<input type="checkbox"/>	Each <Prisoner> is clearly informed in advance that participation in the research will have no effect on his or her parole
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1.9	<input type="checkbox"/>	One of the following is true: <input type="radio"/> There is no need for follow-up examination or care of subjects after the end of their participation <input type="radio"/> Adequate provision has been made for follow-up examination or care of subjects after the end of their participation, taking into account the varying lengths of individual <Prisoners>' sentences, and for informing subjects of this fact
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2. Notes

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3. Footnotes

3.1	For DHS, EPA, HHS, or VA research certification is required that that the duties of the IRB under this section have been fulfilled.
3.2	<Minimal Risk> has a specific definition when applied to prisoners. See "POLICY: Definitions (HRP-001)"
3.3	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.
3.4	For research subject to DHS, HHS, or VA regulations, the applicable official is the Department Secretary. For research subject to DOD regulations, the applicable official is the Director, Defense, Research, and Engineering.
3.5	OHRP interprets control groups which may not benefit from research to include a control group receiving standard of care that the prisoners would otherwise receive, services as usual, or a placebo.