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|  | Diagram  Description automatically generated | **FORM: Prisoner Certification Checklist for Investigator** |

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| **Date:** |  | | |
| **FHIRB #:** |  | | |
| **RG #:** |  | **Protocol #:** |  |
| **Principal Investigator:** |  | | |
| **Study Title:** |  | | |

**Instructions:**

Complete this form and attach it in Hutch IRB if the research includes research procedures, enrollment, and accessing identifiable information or identifiable biospecimens about prisoners.

NOTE: It is **not** necessary to complete and submit this form if:

1. Your dataset will not have sufficient information about participants to determine whether you have information and/or biospecimens from prisoners included in the research (e.g., there is only a theoretical possibility that there are prisoners).
2. You are requesting a Not Human Research determination.
3. Is this study funded by a federal grant from Department of Health and Human Services (e.g., NIH, NCI, DAIDS, etc)?

Yes → IRB will send a certifying letter to Office of Human Research Protections (OHRP). *Research activities involving prisoners may not commence until OHRP approval is received.*

No → OHRP not involved

1. What categories of permissible research involving prisoners apply to this protocol (check all that apply):

2.a  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;

2.b  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;

2.c  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

2.d  Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well being of the subject.

Note: In cases in which the study requires 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 intent to approve such research.

Note regarding **donor participants**: OHRP has provided feedback that it does not consider donors to be appropriate to include under this category of prisoner research. Moving forward, Fred Hutch IRB will not approve the inclusion of a prisoner population who is a donor on the study.

2.e  Research that has as its sole purpose (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. **Please note, under this category of research, you do not need to satisfy the regulatory requirements outlined in question 3 (below). Please proceed to Question 4.**

***(\* Minimal risk – probability and magnitude of physical or psychological harm that was normally encounter in the daily lives, or in the routine medical, dental, or psychological examination of health person.)***

1. Please describe any possible advantages accruing to the prisoner through his or her participation in the study, 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. Are the risks involved in the study commensurate with risks that would be accepted by non-prisoner volunteers?

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1. Are procedures for the selection of participants within the prison fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners? (Unless the principal investigator provides to the IRB justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular study.)

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1. Is the information about the study presented in language which is understandable to the research participant?

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1. Does adequate assurance exist that parole boards will not take into account a prisoner’s participation in the study in making decisions regarding parole, and is each prisoner clearly informed in advance that participation in the study will have no effect on his or her parole?

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1. Could there be a need for follow-up examination or care of participants after the end of their participation? If so, have adequate provisions been made for such examination or care, taking into account the varying lengths of individual prisoners’ sentences, and for informing participants of this fact?

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