**IRB Review Checklist**

IRB File No.: **«Tracking\_Number»**

**Attachment 2 – Prisoners [**[**45 CFR 46, Subpart C**](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-c/index.html)**]**

*Prisoner* means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing. [[45 CFR 46.303(c)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-c/index.html#46.303)]

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| Along with the requirements of [45 CFR 46, Subpart A](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#subparta), an IRB must make the following seven additional findings required by the regulations ([45 CFR 46.305](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-c/index.html#46.305)) in order to approve research involving prisoners: |
| 1. The research under review represents one or more of the four categories of research permissible under [45 CFR 46.306(a)(2)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-c/index.html#46.306):  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.  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.  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).  Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject.  Does not apply - document justification in the comments section.  \*For research involving prisoners, the regulations at [45 CFR 46.303(d)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-c/index.html#46.303) define “minimal risk” as “*the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.”* |
| 2. 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 receiving such advantages in the limited-choice prison environment is impaired.  Yes  No – document justification in the comments section |
| 3. The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers.  Yes  No – document justification in the comments section |
| 4. Procedures for the selection of subjects within the prison are fair to all prisoners **and** immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides the IRB with written justification for following some other procedures, control subjects must be selected randomly from the group of available prisoners that meet the characteristics needed for that particular research proposal.  Yes  No – document justification in the comments section |
| 5. The information is presented in language that is understandable to the subject population.  Yes  No – document justification in the comments section |
| 6. Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, **and** each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole.  Yes  No – document justification in the comments section |
| 7. Where the IRB finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.  Yes  No – document justification in the comments section  Not applicable |
| Comments: |
| Signature of Reviewer\*: |

\*For Full Board Review, only IRB Chair or Vice Chair Signature is required.