**For studies involving prisoners,** check the box beside the section that best fits your research, and address the issues that immediately follow as they apply to your research by typing in the line provided.

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|  | **Section 1. Research Involving Prisoners [**[**45 CFR 46 Subpart C**](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#subpartc)**]**  Definitions related to research involving prisoners - "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; or * Individuals detained pending arraignment, trial, or sentencing.   **Note: Probation and parole are usually NOT considered as incarceration.**  **Note: “**[**Minimal risk**](https://www.uthscsa.edu/vpr/services/glossary#Minimal-Risk)**” under Subpart C of the federal regulations is the probability and magnitude of physical and psychological harm as normally encountered in the routine medical, dental, or psychological examination of healthy persons.**  Check here to confirm understanding of these definitions |
| **A.** | **Place a check in the box beside the** [**category**](http://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/Prisoner-Research/index.html) **that best represents the research and provide the rationale for that choice: [**§[46.306](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.306)**]**    The research is a study of the possible causes, effects, and processes of incarceration, and of criminal behavior. [§46.306(2)(i)]  Explain why the research is no more than minimal risk and represents no more than inconvenience to the participants.  The research is a study of prisons as institutional structures or of prisoners as incarcerated persons. [§46.306(2)(ii)]  Explain why the research is no more than minimal risk and represents no more than inconvenience to the participants.  The study represents research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other 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).  [§46.306(2)(iii)]  Explain the condition(s) that will be studied and provide the rationale.  The study represents research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. [§46.306(iv]  Explain the research practices used in this study and how they are intended to improve the health and well-being of the participants.  The study has as its sole purpose either: (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. (This category is not included in Subpart C, but is permitted under the HHS Secretarial waiver for certain epidemiological research if the research presents no more than minimal risk and no more than inconvenience to the prisoner- participants, and prisoners are not a particular focus of the research (As published in the Federal Register / Vol. 68, No. 119 / Friday, June 20, 2003 / Rules and Regulations, page 36929.)  Explain the purpose of the study to demonstrate that it is encompassed by either (i) or (ii): |
| **B.** | **Explain whether or not persons considered prisoners will be randomized into a control group**.  If “Yes,” will the control group participants potentially benefit from the research? |
| **C.** | **How does each of the following required conditions apply to the research [§**[**46.305**](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.305)**]?**    1. Are there 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, that are 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 prisoner is impaired?  No  Yes  N/A  1.1 Explain the possible advantages that can be expected for prisoner participants. |
|  | 2. Are the risks involved in the research commensurate with the risks that would be accepted by participants who are not prisoners?  No  Yes  2.1 Explain the possible risks that can be reasonably expected for prisoner participants. |
| **.** | 3. Subject Selection:  Are the procedures for the selection of participants within the prison fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners?  No  Yes  3.1 Explain how prisoners will be selected for participation in this research study, specifying the strategies  to ensure fairness and to avert arbitrary intervention by prison authorities or prisoners.  3.2 If prisoners are not the targeted population, explain the importance of continuing to intervene, interact,  or collect identifiable private information during a participant’s incarceration.  N/A (check here if not applicable)  3.3 If there is a control group, will the control subjects be selected randomly from the group of available  prisoners who meet the characteristics needed for the research project?  No  Yes  N/A (no control group)  If “No,” please discuss the selection of the control subjects. |
|  | 4. Discuss the strategies that will be used to ensure that the information about the study will be presented in a language that is understandable to the participant population. |
|  | 5. Explain what assurances have been made to ensure parole boards will not take into account a prisoner's participation in the research when making decisions regarding parole.  5.1 Explain how each prisoner will be clearly informed in advance that participation in the research will  have no effect on decisions to be made about his/her parole. |
|  | 6. Does the PI plan for or expect there to be a need for follow-up exam(s) or care of participants after the end of their participation?  No  Yes  6.1 If “Yes,” Describe the follow-up planned.  6.1.a Explain what provisions have been made for follow-up, including how the varying lengths  of individual prisoners’ sentences have been taken into account.  6.1.b Explain how you will communicate this to the prisoner participants. |
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