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| Appendix: PrisonersInstructions for using this Appendix:If the study will enroll prisoners, complete this form as part of your submission to the Institutional Review Board (IRB). This form documents the information required to ensure research is performed in accordance with the NYU Langone Human Research Protections Policy and Procedure Manual, available on the Human Research Protections (HRP) website. This policy applies to all research involving human subjects if NYU Langone Health faculty, staff, students, or facilities are involved, regardless of sponsorship and/or performance site.*[Remove the instructional text above prior to submitting the appendix]*  |
| Subject population | [ ]  Individuals involuntarily confined or detained in a penal institution[ ]  Individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution; explain:      [ ]  Individuals detained pending arraignment, trial, or sentencing; explain:      [ ]  Other individuals involuntarily detained under a criminal or civil statute; explain:       |
| List where the prisoners are located |       | You have permission from the facility and the appropriate authorities  | [ ]  Yes; documentation is attached[ ]  No; permission has been sought and is pending |
| One or more of the subjects in this research are minors in the jurisdiction where the research is taking place | [ ]  Yes; *Appendix: Children* also attached [ ]  No |  |  |
| Allowable CategoriesCheck the category below that best represents the nature of the research and the degree of risk and benefit to which the prisoners in this study will be exposed. In order for the research to be approved, it must fall into one of the below 4 categories.Note: The definition of minimal risk for prisoners is slightly different than the definition for other subjects. The definition of minimal risk for research involving prisoners is given in 46.303(d), is as follows:Minimal risk is 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. |
| Category 1 | [ ]  The study of the possible causes, effects, and processes of incarceration, and of criminal behavior, where the study presents no more than minimal risk and no more than inconvenience to the subjects; explain:       |
| Category 2 | [ ]  The study of prisons as institutional structures or of prisoners as incarcerated persons, where the study presents no more than minimal risk and no more than inconvenience to the subjects; explain:       |
| Category 3 | [ ]  The study of conditions particularly affecting prisoners as a class (for example, research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults, or vaccine trials and other research on diseases which are much more prevalent in prisons than elsewhere); explain:       |
| Category 4 | [ ]  The study of practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject; explain:      Does the study involve a control group which will not receive a benefit from being in the study? [ ]  Yes; additional procedures are required for approval. Contact the IRB for more information[ ]  No |
| Coercive Considerations  |
| The advantage in taking part in this study may coerce participationIE: the possible advantages accruing to the prisoner through his or her participation in the study, when compared to the general prisoner population (living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison) are of such a magnitude that their ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison may be impaired | [ ]  Yes (or “possible”); explain:      [ ]  No |
| The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers | [ ]  Yes[ ]  No; explain:       |
| The procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners | [ ]  Yes[ ]  No; explain:  |
| The information presented in language which is understandable to the subject population | [ ]  Yes[ ]  No; explain:       |
| Adequate assurance exists that parole board will not take into account a prisoner's participation in the research when making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on their parole | [ ]  Yes[ ]  No; explain:       |
| There may be a need for follow-up examination or care of subjects after the end of their participation | [ ]  Yes; adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing subjects of this fact; describe:      [ ]  No |