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| **Protocol Information** |
| **PI:**       |
| **IRB #:**      **Title:**       |
| **IRB Analyst:**       | **Date of Analyst Review:**       |
| **IRB Reviewer:**       |
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| **Subpart C: Additional Protections for Prisoners** |
| **Additional Conditions for Approval: §46.305** (all 7 conditions must be met) |
| [ ]  Yes [ ]  No | (1) Research meets one of the categories in §46.306(a)(2) [see next page] |
| [ ]  Yes [ ]  No | (2) Any possible advantage accruing to the prisoner through 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 magnitude that his or her ability to weigh the risks of the research against the value of the limited choice environment of the prison are impaired |
| [ ]  Yes [ ]  No | (3) The risks are commensurate with risks that would be accepted by non-prisoner research participants |
| [ ]  Yes [ ]  No | (4) Procedures for the selection of subjects are fair to all prisoners and are immune from arbitrary intervention by the prison authorities or prisoners. Unless the principal investigator provides justification in writing for following some other procedures, control subjects are selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project. |
| [ ]  Yes [ ]  No | (5) The information will be presented in language that is understandable to the participants |
| [ ]  Yes [ ]  No [ ]  N/A | (6) Adequate assurance exists that parole boards will not taken into account a prisoner’s participation in making decisions about parole and each prisoner is informed in advance that participation will have no effect on his/her parole. |
| [ ]  Yes [ ]  No [ ]  N/A | (7) Adequate provisions are in place (when applicable) for follow-up care.  |
| **Permitted Research Involving Prisoners §46.306(a)(2)** (one of the 4 categories must be indicated) |
| [ ]  Yes [ ]  No | (i) Study of possible causes, effects and processes of incarceration and of criminal behavior, provided that the study represents no more than minimal risk and no more than minimal inconvenience |
| [ ]  Yes [ ]  No | (ii) 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.  |
| [ ]  Yes [ ]  No | (iii) Research on conditions particularly affecting prisoners as a class. Research may NOT proceed until the Secretary, DHHS has consulted with appropriate experts and published the findings in the Federal Register. |
| [ ]  Yes [ ]  No | (iv)(a) Research on practices, both innovative and accepted which have the intent and reasonable probability of improving the health or well-being of the subject(s).  |
| [ ]  Yes [ ]  No [ ]  N/A |  (b) If subjects will be assigned to control group(s) that will not benefit from the research, the study may NOT proceed until the Secretary, DHHS has consulted with appropriate experts and published the findings in the Federal Register.  |
| **Comments Regarding Adequacy of Plan for Consulting Secretary, DHHS** (if applicable) |
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| **Summary plus Required and Recommended Stipulations (if any)** |
| **Additional Comments** |
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| **Analyst’s Proposed Stipulations** |
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| **IRB Reviewer’s Stipulations** |
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| **Approval, Modification or Disapproval** |
| [ ]  Approval [ ]  Modifications Required[ ]  Disapproval | **Stipulations to be reviewed by:**[ ]  Review by Chair or Designee:      [ ]  Full Committee |
| **IRB Reviewer Name/Signature:**       | **Date:**       |