**FORM 5.1A CHECKLIST** – **REQUIREMENTS FOR RESEARCH INVOLVING PRISONERS**

**INVESTIGATOR: IDI REC #**

**STUDY TITLE**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  | **Yes** | **No** | **N/A** | **Comments** |
| 1 | Does the research have the intent, and reasonable probability, of improving the health and wellbeing of the participants themselves? OR |  |  |  | If the answer to one or both of these |
| 2 | If the research does NOT have the intent, and reasonable probability, of improving the health and wellbeing of the participants themselves, is the research on conditions particularly affecting prisoners as a class (e.g., vaccine trials on hepatitis) |  |  |  | Questions is yes, continue.  If the answer to both questions is NO, the study cannot be approved.  If the answer to question 2 is yes, the answer to this question must be YES as well.  If the answer to ques. 3 is yes, the answer to either ques. 3a or 3b must be YES. |
| 2a | Has the Secretary, HHS, or designee published notice in the Federal Register of its intent to approve such research? |  |  |  |
| 3 | Is there a control group? |  |  |  |
| 3a | Are control participants selected randomly from the group of eligible prisoners for the research project? |  |  |  |
| 3b | If not, has the Investigator provided justification in writing for?  following some other procedures, |  |  |  |
| 4 | Any possible advantages 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 prison, are not of such a magnitude that the prisoner's ability to weigh  the risks and benefits of the research in the limited-choice environment of the prison is impaired. |  |  |  |
| 5 | The probability and magnitude of **physical or psychological** harm is no more than what is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of **healthy persons**. The risks involved in the research are commensurate with  risks that would be accepted by non-prison volunteers. |  |  |  |
| 6 | Selection procedures within the prison are fair to all prisoners and immune from arbitrary intervention by prison authority or prisoners. |  |  |  |
| 7 | Any information given to participants is presented in language that is appropriate for the participant population. |  |  |  |
| 8 | Adequate assurance exists that parole board(s) 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 clinical investigation will have no effect on his/her  parole. |  |  |  |
| 9 | Where there is need for follow-up examination or care of participants after the end of their participation in the research, adequate provision has been made for such examination or care, taking into account the varying  lengths of prisoner sentences, and for informing participants of this fact. |  |  |  |

The proposed research appears to be:

* (A) A study of the possible causes, effects, and processes of incarceration, and of criminal behavior that presents no more than minimal risk and no more than inconvenience to the participants,
* (B) A study of prisons as institutional structures or of prisoners as incarcerated persons, that presents no more than minimal risk and no more than inconvenience to the participants;
* (C) A study of a condition or conditions particularly affecting prisoners as a class
* (D) A study of practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the participant.

**COMMENTS:**

Primary Reviewer Date