

**UMB Human Research Protections Program**  
**Review of Research Involving Prisoners**  
**Checklist #14**

**PROTOCOL NUMBER:** \_\_\_\_\_

**PRINCIPAL INVESTIGATOR:** \_\_\_\_\_

**TITLE OF STUDY:** \_\_\_\_\_

KEY:

Solid box: All items in the box must be true

Dotted box: One item in the box must be true

**All of the following are true:**

**(1)** The research under review represents one of the following categories of permissible research:

**(2) Category (a):** Both of the following are true:

**(3)** The research involves the study of the possible causes, effects, and processes of incarceration, and of criminal behavior.

(State reasons here)

**(4)** The research presents no more than minimal risk and no more than inconvenience to the participants.

(State reasons here)

**(5) Category (b):** Both of the following are true:

**(6)** The research involves the study of prisons as institutional structures or of prisoners as incarcerated persons.

(State reasons here)

**(7)** The research presents no more than minimal risk and no more than inconvenience to the participants.

(State reasons here)

**(8) Category (c):** Both of the following are true:

**(9)** The research is 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).

(State reasons here)

**(Cont.)**

- (10)** All of the following are true:
  - (11)** The research is conducted or supported by DHHS.
  - (12)** The Secretary has consulted with appropriate experts including experts in penology, medicine, and ethics.
  - (13)** The Secretary has published notice, in the Federal Register, of his intent to approve such research.

**(14) Category (d):** Both of the following are true:

- (15)** The research is on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the participant.

(State reasons here)

**(16)** One of the following is true:

- (17)** The research does not require the assignment of prisoners to control groups that may not benefit from the research.

**(18)** All of the following are true:

- (19)** The research is conducted or supported by DHHS.
- (20)** The Secretary has consulted with appropriate experts including experts in penology, medicine, and ethics.
- (21)** The Secretary has published notice, in the Federal Register, of his intent to approve such research.

**(22) Category (e):** Both of the following are true:

- (23)** The sole purposes of the research are one or more of the following:

- (24)** To describe the prevalence or incidence of a disease by identifying all cases

(State reasons here)

- (25)** To study potential risk factor associations for a disease.

(State reasons here)

**(26)** Both of the following are true:

- (27)** The research presents no more than minimal risk and no more than inconvenience to the prisoner-participants.

(State reasons here)

**(Cont.)**

- (28)** Prisoners are not a particular focus of the research.

(State reasons here)

- (29)** One of the following is true:

- (30)** 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 such advantages in the limited choice environment of the prison is impaired.

(State reasons here)

- (31)** The research under review represents permissible category (e) above.

- (32)** The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers.

(State reasons here)

- (33)** Procedures for the selection of participants within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners.

(State reasons here)

- (34)** One of the following is true:

- (35)** Control participants will be selected randomly from the group of available prisoners who meet the characteristics needed for the research project.
- (36)** The principal investigator has provided justification to the IRB in writing for following other procedures.

- (37)** The information is presented in language that is understandable to the participant population.

(State reasons here)

- (38)** Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole.

(State reasons here)

**(Cont.)**

- (39)** Each prisoner will be clearly informed in advance that participation in the research will have no effect on his or her parole.

(State reasons here)

- (40)** 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.

(State reasons here)

- (41)** One of the following is true:

- (42)** The research is not conducted or supported by DHHS.

- (43)** Both of the following are true:

- (44)** The institution responsible for the conduct of the research has certified to the Secretary that the Institutional Review Board has approved the research.
- (45)** In the judgment of the Secretary the proposed research involves solely one of the permissible categories.

The proposed involvement of prisoners is:  Approvable  
 Not approvable

Signed \_\_\_\_\_

Dated \_\_\_\_\_

Reference: 45 CR 46.306(a)(2) and UMB HRPP Policies and Procedures 9B: Special Categories of Research: Prisoners