INSTITUTIONAL REVIEW BOARD REVIEW OF RESEARCH INVOLVING PRISONERS

DESCRIPTION

Prisoners may be under constraints because of their incarceration that could affect their ability to make a truly voluntary and un-coerced decision whether or not to participate as subjects in research. The University of Cincinnati (UC) Institutional Review Board (IRB) will ensure that appropriate additional protections are provided so the rights and welfare of this population are maintained.

PRISONERS

- Includes any individual involuntarily confined or detained in a penal institution or who is sentenced to such an institution under a criminal or civil statute.

- Includes individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution.

- Includes individuals detained pending arraignment, trial, or sentencing.

- Includes individuals confined to a half-way house, a juvenile facility, or home incarceration whose ability to leave the facility is restricted.

- Does not include individuals participating in non-residential treatment or supervision, including probation or parole, who are residing in the community.

RESPONSIBILITY

The IRB Chair or designee shall determine whether or not individuals who meet the definition of prisoners will be recruited as participants in the research study and, if so, shall ensure that review processes described in Human Research Protection Program (HRPP) Policy V.01 Protecting Vulnerable Populations in Human Subjects Research are followed.

HRPP staff shall ensure that required documentation is maintained in the IRB's study records and meeting minutes.
PROCESS

DEFINITIONS

Probation: Probation is an alternative to prison. It is given instead of a prison sentence and, as such, tends to place more rigid obligations upon the individual serving the term. Probationers and individuals wearing monitoring devices are generally not considered to be prisoners (because they "are residing in the community").

Parole: Parole is the early release from prison, serving the remainder of a sentence outside of prison. Parolees are still considered to be serving their sentences (but would not be considered to be prisoners if they "are residing in the community").

Commitment for Psychiatric Treatment:

Individuals with psychiatric illnesses who have been committed involuntarily to an institution as an alternative to a criminal prosecution or incarceration are prisoners.

Individuals who have been voluntarily admitted to an institution for treatment of a psychiatric illness, or who have been civilly committed to non-penal institutions for treatment because their illness makes them a danger to themselves or others, are not prisoners.

Prisoner Advocate: A prisoner advocate is a member of the IRB who has been a prisoner or who has an understanding and appreciation of prison conditions from the perspective of the prisoner. It is not appropriate for a correctional facility employee or an individual involved in prosecuting offenders to serve as a prisoner advocate.

Minimal Risk: 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.

CONSIDERATIONS

1. Is this vulnerable population specifically targeted for enrollment?

2. Is it likely that some participants may become incarcerated during their study participation?
3. Does the scientific or scholarly design of the study support inclusion of this vulnerable population?

4. Are there risks of coercion or harm to the study's participants that are related to being a prisoner?

5. Will the vulnerable population receive direct benefit from participating in the research?

6. Are the population-specific risks reasonable in relation to the anticipated benefits?

7. Are protections adequate to avoid coercion during recruitment and consenting of this vulnerable population?

8. Are these vulnerable participants able to withdraw from the study without penalty, undue influence to remain in the study, or loss of benefits they would otherwise have?

**REQUIREMENTS OF IRB REVIEW**

1. A majority of the IRB members shall have no association with the prison(s) and/or prisoners involved in the research, apart from their membership on the IRB.

2. The IRB Chair or designee shall ensure that an IRB member who is a prisoner advocate is included in the review of any research study involving prisoners. This includes all phases of IRB review, including initial review, continuing review, review of amendments and review of reports of unanticipated problems involving risks to subjects. The prisoner representative must be a voting member of the IRB. The prisoner representative may be listed as an alternative member who becomes a voting member when needed. The prisoner representative must review research involving prisoners, focusing on the requirements in 45CFR46 Subpart C or equivalent protections. The prisoner representative must receive all review materials pertaining to the research (same as primary reviewer). Minor modifications to research may be reviewed using the expedited procedure, based on the type of modification. Modifications involving more than a minor change reviewed by the convened IRB – must use the same procedures for initial review including the responsibility of the prisoner representative to review the modification and participate in the meeting (as described above). The same procedures for initial review must be used for continuing review including the responsibility of the prisoner representative to review all materials and participate in the meeting (as described above). If no participants have
been enrolled, the research may receive continuing review using the expedited procedure under expedited category #8.

3. For research conducted within the Bureau of Prisons, implementation of Bureau programmatic or operational initiatives made through pilot projects is not considered to be research.

4. Based on 45CFR46.306 (b), research involving prisoners is not eligible for exemption under 45CFR46.101 (b).

5. Research involving interaction with prisoners may qualify for expedited review if it involves no more than minimal risk and meets the criteria listed in 45CFR46 Subparts A and C, as determined by the IRB Chair or designee. The prisoner representative must participate in such expedited review by reviewing the research study submission as a reviewer. This may be as the sole reviewer or in addition to another reviewer, as appropriate. The prisoner representative must concur with the determination that the research involves no greater than minimal risk. All other prisoner research must be reviewed at a convened meeting of the IRB where the prisoner advocate is present for the discussion and vote. Review of modifications and continuing review must use the same procedures for initial review using this including the responsibility of the prisoner representative to review the modification and participate in the meeting. Continuing review must use the same procedures for initial review including the responsibility of the prisoner representative to review the continuing review materials and participate in the meeting. If no participants have been enrolled the research may receive continuing review using the expedited procedure under expedited category #8.

6. Research that does not involve interaction with prisoners (e.g., existing data, record review) may qualify for expedited review if a determination is made that the research involves no greater than minimal risk for the prison population being studies. The review by a prisoner representative is not required. The prisoner representative may review the research as a reviewer or consultant if designated by the IRB Chair. Review of modifications and continuing review must use the same procedures as initial review.

REQUIREMENTS OF PRISONER RESEARCH CONDUCTED AT VAMC

Research involving prisoners may not be conducted by Veterans Administration medical Center (VAMC) investigators while on official duty or at the CVAMC unless a waiver has been granted by the Chief Research and Development Officer (CRADO) and criteria stipulated by the Department of Veterans Affairs have been met. If such a waiver is granted
by the CRADO, the research must be in accordance with applicable Federal regulations pertaining to prisoners as research subjects (see 45 CFR 46, Subpart C 46.301–46.306, Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects).

In cases involving VAMC funded research, the UC IRB will certify to the VAMC CRADO that the review of research involving prisoners as research subjects has been conducted in accordance with these requirements. The research may not be conducted without the approval of the CRADO.

International research is not initiated unless permission is obtained from the CRADO or designee; the CRADO, or designee, will not grant permission for an international research study involving prisoners as research participants.

INDIVIDUALS WHO BECOME PRISONERS AFTER THE RESEARCH HAS BEGUN

It is possible that a participant may become a prisoner after the research has begun but the protocol was not reviewed according to 45CFR46 Subpart C. The researcher may take either of the following actions.

1. Drop the participant from the study, if doing so would not put the participant at risk of harm. The researcher then may either leave the study as approved, without prisoner participants, or submit an amendment request to the IRB to have the study approved for prisoners in the future.

2. If the participant cannot be withdrawn for health or safety reasons submit an amendment to the IRB requesting to have the study approved for prisoners and keep the participant in the study. This option should be chosen if removing the prisoner from the study would put the participant at risk of harm. The rationale for keeping the prisoner in the study must be included in the amendment request. The IRB will review the research under 45CFR46Subpart C. If the requirements of 45CFR46Subpart C cannot be met, but it is in the best interest of the participant to remain in the study, the PI must inform the IRB and provide a justified request to keep the study participant enrolled.

If it is likely that members of the targeted population will become incarcerated, the IRB encourages the researcher to have the study approved for prisoner participants from the outset to avoid delays and complications later in the study.
DETERMINATIONS REQUIRING DOCUMENTATION

The IRB Chair or designee shall document the IRB’s determinations regarding the following requirements for approval of research involving prisoners. No research involving prisoners shall be approved unless it meets the appropriate criteria listed below.

1. The research under review represents one of the following categories of research permissible under 45CFR46.306(a)(2).

   a. A study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

   b. A 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;

   c. Research 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) provided that the study may proceed only after the Secretary has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of his intent to approve such research; or

   d. Research on practices, both innovative and accepted, that have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of the intent to approve such research.

   e. Epidemiologic research that has as its sole purpose

      (i) to describe the prevalence or incidence of a disease by identifying all cases, or

      (ii) to study specific potential risk factor associations for a disease.
2. 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;

3. The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers;

4. Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the PI justifies in writing to the IRB following other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;

5. The information is presented in language that is understandable to the subject population;

6. Adequate assurance exists that parole boards 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 research will have no effect on his or her parole; and

7. 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.

RESEARCH INVOLVING PRISONERS FUNDED BY THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

When the IRB has approved research funded by the Department of Health and Human Services (HHS) that includes prisoners, the Institutional Official (IO) shall certify to the Secretary of HHS that the duties of the Board under 45CFR46 Subparts A and C have been fulfilled.

This certification shall be done by letter to the Office of Human Research Protections (OHRP) at the following address.
The certification letter shall contain the following information.

1. UC's institutional name and address, which may be in the letterhead

2. UC's IRB registration name and FWA number.

3. Research study title, protocol number and date of approval

4. A statement that the IRB has reviewed and approved the research according to the University of Cincinnati Human Research Protection Program Procedure 331 Institutional Review Board Review of Research Involving Prisoners and 45 CFR 46 Subparts A and C

5. Related federal grant title(s) and identification number(s)

6. PI's name and funding agency name

7. A statement that the IRB has made the seven determinations required under 45 CFR 46.305(a). The §46.306(a)(2) category and description shall be specified in the first determination on the list

8. A statement of the risk level and the potential for direct benefit to participants

9. A summary of the research and rationale for including prisoners in the study

10. Copies of the following documents shall be attached

- Attachment A: IRB approved protocol
- Attachment B: IND exempt letter for the drug being used and any other correspondence from the FDA about that drug.
- Attachment C: IRB approved consent document
Attachment D: Checklist for Principal Investigators to Complete Regarding Research Involving Prisoners
Attachment E: Prisoner review section completed by the IRB reviewer and the Subpart C determinations made by the IRB
Attachment F: Notice of grant award, including grant specific restrictions and project officer’s contact information
Attachment G: Certificate of Confidentiality
Attachment H: Face page of the grant
Attachment I: Background section of the grant
Attachment J: Methods section from the grant
Attachment K: Excerpts from the minutes of the IRB meeting(s) when this research was reviewed
Attachment L: UC HRPP Procedure 331 Institutional Review Board Review of Research Involving Prisoners

The Secretary of Health and Human Services must determine that the proposed research falls within the categories of research permissible under 45 CFR 46.306(a)(2). The research may not proceed until OHRP issues its approval in writing to UC.

RESEARCH INVOLVING PRISONERS FUNDED BY THE DEPARTMENT OF JUSTICE AND THE BUREAU OF PRISONS

When research is conducted within the Bureau of Prisons, the requirements of 28 CFR Part 512 will be followed. When following the Department of Justice regulations, the requirements of 28 CFR Part 46 will be followed. The researcher will complete and submit a checklist confirming the following:

- The project does not involve medical experimentation, cosmetic research, or pharmaceutical testing.
- The research design is compatible with both the operation of prison facilities and protection of human subjects.
- The research will observe the rules of the institution or office in which the research is conducted.
- Non-Prison Bureau employees acting as researchers will sign a statement in which he/she agrees to adhere to the provisions of 28 CFR Part 512.
- The research proposal will be reviewed by the Prison Bureau Research Review Board.
- The project has an adequate research design and will contribute to the advancement of knowledge about corrections.
Applicable Regulations and Documents:

45 CFR 46 Subpart C Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects
OHRP Guidance dated 1-20-11  http://answers.hhs.gov/ohrp/questions/7226
VHA Handbook 1200.5 (May 2, 2012), paragraphs 12 and 47
Department of Justice and Bureau of Prisons Research Checklist
28 CFR Part 512
Policy V.01 Protecting Vulnerable Populations in Human Subjects Research
Checklist for Principal Investigators to Complete Regarding Research Involving Prisoners
Prisoner IRB Approval Certification to DHHS letter template (4-18-14).doc

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Date Adopted: **March 2015**  Signature: **signed copy on file**