Summary on Prisoners Regulations
45 CFR 46 Subpart C
OHRP Prisoner Research FAQ

Applicability

- Subpart C applies whenever any human subject becomes a prisoner at any time during the study

Definition: Prisoner

Involuntarily confined/detained in penal institution or other type of incarceration*. Per OHRP: Whether subject is a "prisoner" depends on degree of freedom given to individual. See definition and statement from the Commission of the KY Department of Corrections (DOC), below for guidance in making the determination.

For studies involving prisoners, or for studies recruiting subjects at risk of becoming involuntarily confined/ detained in a penal institution during the research (i.e., subjects with substance abuse history), complete this form and include it with your IRB application submission.

Please note: Under the Kentucky Administrative Regulations applicable to county jails (not federal prisons), inmates are **not permitted** to participate in medical research (i.e. drug, device, biologic clinical trials). For assistance with applying state law to your research, contact ORI at 859-257-9428, or Katherine Adams, Legal Counsel, at 859-257-2936.

Membership

- Majority members should have no association with prison
- One member must be a prisoner or prisoner representative with appropriate background or expertise
- Prisoner representative must participate in all types of review (IR, CR, MR, AE)

Conditions of Approval

To approve the IRB must find that the following **7 conditions** are met and document justification for each finding:

1. Advantages through participation, when compared to current situation, not so great that they impair prisoners' ability to weigh risks.
2. Risks same as those would be accepted by non-prisoners.
3. Procedures for selection fair to all prisoners. Immune from intervention by prison authorities in prisons; control subjects must be randomly selected.
4. Language understandable to prisoners.
5. Parole boards cannot take into consideration participation. Informed consent must state participation will not impact parole.
6. Studies that need follow up, provision for follow up made including considering length of individual sentences; prisoner must be included in informed consent.
7. IRB must find research falls in one of the following **4 categories** and must document rationale for category selected:
   a) "Minimal risk" and "no more than inconvenience" to subjects AND is a study of causes, effects and process of incarceration and of criminal behavior [OHRP report required if HHS funded]
   b) "Minimal risk" and "no more than inconvenience" to subjects AND is a study of prisons as institutional structures or of prisoners as incarcerated persons [OHRP report required if HHS funded]
   c) Research on conditions affecting prisoners as a class but secretary must first consult with experts and publish FR/so IRB has to report to OHRP (if HHS funded)
   d) Research with intent and probability to improve health or well-being of subject; if research includes control groups (placebo) secretary must consult or publish FR – so IRB must inform OHRP (if HHS funded)

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Waiver: To Allow DHHS Epidemiology Research That Do Not Fit In Existing Categories

- Applies to epidemiology research sole purposes:
  a) to describe prevalence/incidence of a disease or
  b) to study potential risk factor for a disease
- IRB must apply 7 conditions
- IRB must determine and document:
  - No more than minimal risk and no more than inconvenience to prisoner – subjects
  - Prisoners not focus of research

Definition: "Minimal Risk"

Definition of minimal risk is different than the one used in Subparts A, B and D [46.303(d)]

- Refers to "physical or psychological" harm as opposed to "harm" or "discomfort"
- Uses "healthy" persons standard

Certification Letter to OHRP for HHS Funded Research ONLY

- Letter must be submitted to OHRP for all HHS projects involving prisoners including studies that fall under waiver
- Include research proposal (i.e., IRB approved protocol, HHS grant application, IRB application forms, information requested by IRB at IR)
- Include category selected and IRB justification for category selected
- Waiver Epidemiology Research: Also include IRB determination and justification regarding
  a) minimal risk/inconvenience
  b) prisoner not focus
- Research cannot be initiated until OHRP issues approval

***Prisoner**: An individual involuntarily confined in a penal institution, including persons: (1) sentenced under a criminal or civil statue; (2) **detained** pending arraignment, trial, or sentencing; and (3) **detained** in other facilities (e.g., for drug detoxification or treatment of alcoholism) under statutes or commitment procedures providing such alternatives to criminal prosecution or incarceration in a penal institution [45 CFR 46.303(c)]. Note: Probation and parole are usually NOT considered as incarceration.*

According to the Commission of the KY Dept. of Corrections (DOC), In KY, prisoners may be housed in community corrections centers if they have the proper custody. If an offender with a monitoring device is serving home incarceration, he/she is an inmate and their home is an extension of their incarceration. However, if the offender is on parole with a monitoring device, they are not considered an inmate. Be aware that residential treatment programs may house BOTH individuals who are completing substance abuse programs that remain under state custody considered as prisoners, as well as parolees completing treatment.

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REQUIREMENTS FOR RESEARCH INVOLVING PRISONERS AS SUBJECTS

There are special federal regulations which govern research involving prisoners enrolled as subjects. Subpart C of 45 Code of Federal Regulation (CFR) 46 applies whenever any human subject is a prisoner. A prisoner is defined as a person who is involuntarily confined/detained in a penal institution. If it is unclear if a person is deemed a "prisoner," check with the Office for Human Research Protection (OHRP) for a determination.

When the IRB reviews study protocols that will involve the use of prisoners as participants, a prisoner representative must participate in all types of these reviews (e.g., initial, continuation, modification, and adverse events). In order for the IRB to approve a study, there are seven conditions that must be met and the research must fit into one of four categories. Minimal risk with respect to prisoners, is different from that used in Subparts A, B, and D [46.303(d)]. The difference is, the "risk" refers to physical or psychological harm as opposed to harm or discomfort; and it uses the healthy person standard.

A certification report must be submitted to OHRP for all HHS funded projects involving prisoners. A certification letter from OHRP must be received before a research study can commence. Specific DHHS epidemiology research may be eligible for a waiver. Contact the Office of Research Integrity (ORI) at 257-9428 for further information.

Please note, per Kentucky Administrative Regulation (501 KAR 10:090) which sets forth requirements for delivery of medical services in jails, inmates are not permitted to participate in medical research (i.e. drug, device, biologic clinical trials). This state law does not apply to inmates of federal prisons.

REQUIREMENTS WHEN A SUBJECT BECOMES A PRISONER

If a human subject **becomes a prisoner** during a study, it is crucial that the IRB is contacted immediately because additional review is necessary to comply with 45 CFR 46 Subpart C. A certification report may be required to be submitted to the DHHS.

Prisoner is defined by DHHS regulations at 45 CFR 46 as "any individual involuntarily confined or detained in a penal institution". The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

For a summary of 45 CFR 46 Subpart C prepared by the ORI or a copy of the actual regulation and/or the guidance document relating to the regulation, please contact the ORI at 859-257-9428.

In the event a subject enrolled in medical research (i.e. drug, device, biologic clinical trials) becomes housed in a county jail during the course of the study (does not apply if subject is housed in a federal prison), state law pertaining to medical services for inmates may require that the subject discontinue participation in the study. Please contact the ORI immediately should this occur.