

Grand Valley State University Human Research Review Committee Procedure	
Subject: <i>Research on Prisoners</i>	
Section: 17.0	This procedure supersedes those previously drafted
Initially adopted as procedure on June 18, 2007	Approved by: Dean of Graduate Studies and Grants Administration, 11-15-2007.
Related Sections:	

. Research involving prisoners is permissible only if the research involves one or more of four permissible categories, or if the research meets the criteria described in an HHS Secretarial waiver that applies to certain epidemiological research (68 FR 36929, June 20, 2003): The first two categories are

- (i) the study of the possible causes, effects, and processes of incarceration, and of criminal behavior, and
- (ii) the study of prisons as institutional structures or of prisoners as incarcerated persons. Research in these two categories is permissible only if the study presents no more than minimal risk, and no more than inconvenience to the subjects (45 CFR 46.306(a)(2)).
- (iii) The third category is research on conditions particularly affecting prisoners as a class, such as vaccine trials and other research on hepatitis (more prevalent in prisons than elsewhere), and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults. Research in this category may proceed only after the HHS Secretary has consulted with appropriate experts, including experts in penology, medicine, and ethics, and has published notice in the Federal Register of his or her intent to approve the research (45 CFR 46.306(a)(2)).

- (iv) The fourth category is research on practices, either innovative or accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In this category, if the HRRC-approved proposal is a study in which some prisoners will be assigned to a control group and thus may not benefit from their participation in research, such research may proceed only after the HHS Secretary has consulted with appropriate experts, including experts in penology, medicine, and ethics, and has published notice in the Federal Register of his or her intent to approve the research (45 CFR 46.306(a)(2)). OHRP interprets control groups that may not benefit from research to include a control group receiving a standard of care that the prisoners would otherwise receive, services as usual, or a placebo.

Note: Research proposals in category (iii) or (iv) that are not conducted or supported by HHS do not require a Secretarial consultation, nor do they require certification to OHRP.

The HHS Secretarial waiver for certain epidemiological research conducted or supported by HHS functions as a fifth category of permissible research. The criteria for this category are that the research must have as its sole purpose: (1) to describe the prevalence or incidence of a disease by identifying all cases, or (2) to study potential risk factor associations for a disease.

The institution still must review the research under 45 CFR 46, subpart C and certify to OHRP that an appropriately constituted HRRC has reviewed the proposal and made all other required findings under HHS regulations at 45 CFR 46.305(a) and receive OHRP authorization prior to initiating any research involving prisoners. All of the other requirements of subpart C apply to research in this category.

Along with the requirements of subpart A, the HRRC must meet the following seven additional requirements, or findings, in order to review and approve research involving prisoners:

1. The research under review represents one of the categories of research permissible under 45 CFR 46.306(a)(2);
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 receiving such advantages in the limited-choice prison environment 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 principal investigator provides the HRRC with written justification for following other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research proposal;
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. When the HRRC 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 (45 CFR 46.305(a)). OHRP notes that in order for the HRRC to meet these seven requirements, it must be familiar with the specific conditions in the local prison(s) or jail site(s) that are pertinent to subject protections before approving the proposal for the local site (45 CFR 46.107(a)).

For research involving prisoners, the regulations at 45 CFR 46, subpart C define “minimal risk” as 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 (45 CFR 46.303(d)). However, the wording of the subpart C definition differs in several ways from the definition of “minimal risk” in 45 CFR 46, subpart A, which applies generally to research involving human subjects. The differences are:

- The subpart C definition refers to “physical or psychological harm” rather than “harm or discomfort” as in subpart A.
- The subpart C definition compares the probability and magnitude of harm in the research to the probability and magnitude of those harms normally encountered in daily life, or in “routine medical, dental, or psychological examinations,” rather than in daily life or “routine physical or psychological examinations or tests” as in subpart A.

The subpart C definition identifies “healthy persons” as the comparison group against which the risks of the research should be measured, rather than leaving the comparison group unspecified, as in subpart A. OHRP interprets the term “healthy persons” in this definition as referring to healthy persons who are not prisoners.

Certification to OHRP. For any HHS-conducted or -supported research involving prisoners, the institution(s) engaged in the research must certify to the Secretary (through OHRP) that the HRRC reviewed the research and made the seven findings as required by the regulations (45 CFR 46.305(c) and 46.306(a)(1)). The certification request must be forwarded to OHRP. OHRP then will determine whether the proposed research involves one of the categories of research permissible under 45 CFR 46.306(a)(2), and if so, which one. If OHRP determines that the research involves one of the permissible categories, it will send the institution a letter authorizing the involvement of prisoners in the proposed research.

OHRP will consult with appropriate experts with respect to certain research that falls under paragraphs (iii) and (iv) of 45 CFR 46.306(a)(2). When applicable, OHRP also will publish a

notice of intent to approve such research in the Federal Register. Research involving prisoners may proceed only after receipt of the OHRP authorization letter.

If OHRP determines that the proposed research does not involve one of the permissible categories, it will state in the letter to the institution that such research involving prisoners cannot proceed.

If research is not HHS-conducted or -supported, the institution does not need to submit any certification to OHRP, regardless of whether the institution has chosen to extend the applicability of its FWA and subpart C to all research.

Because of the vulnerability of prisoners, OHRP recommends and GVSU HRRC has adopted as procedure that all research involving prisoners be reviewed by the convened HRRC committee