“**Prisoner** means 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.” (45 CFR 46.303(c))

"**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.” (45 CFR 46.303(d))

Because prisoners may be under constraints as a result of their incarceration which could affect their ability to make a truly voluntary and uncoerced decision whether to participate as subjects in research, it is important to provide additional safeguards for the protection of prisoners (45 CFR 46.302). The Institutional Review Board (IRB) follows the requirements of 45 CFR 46 subpart C and other laws or regulations for equivalent protections.

When research involves prisoners or could involve subjects who become prisoners as defined in the regulations, applications for initial review and renewal may not undergo an expedited review procedure; applications must be taken to the convened IRB for review and discussion. The IRB member prisoner representative must be present if the IRB reviews prisoner research at a convened IRB meeting. In addition, the IRB staff should assign the IRB member prisoner representative as the primary reviewer. Proposed minor changes that would otherwise qualify for expedited review may undergo an expedited review procedure. See the Human Research Protection Program (HRPP) Manual 8-6 “Revisions to an Approved Research Study” and 8-2 “Expedited Review Procedure.” The IRB member(s) reviewing the proposed minor change under the expedited procedure must include a prisoner representative.

**Categories**
The following are the only categories (from 45 CFR 46.306(a)(2)) in which it is permissible to use prisoners as research subjects. The IRB must find that the proposed research falls into one of the permissible categories of research unless the Secretarial waiver described below is applicable.
“(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 or inconvenience to the subjects;

(B) study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk or 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, which 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.”

In addition, there is a HHS Secretarial waiver for certain epidemiological research conducted or supported by HHS. The requirements under subpart C (additional findings, certification) still apply to this category of research. The final action on the waiver was published in the Federal Register, Vol. 68, No. 119 (June 23, 2003) and is provided below.

“Waiv[es] the applicability of 45 CFR 46.305(a)(1) and 45 CFR 46.306 (a)(2) for certain research conducted or supported by DHHS that involves epidemiologic studies that meet the following criteria:

1. In which the sole purposes are
   - (i) To describe the prevalence or incidence of a disease by identifying all cases; or
   - (ii) To study potential risk factor associations for a disease; and

2. Where the institution responsible for the conduct of the research certifies to the Office for Human Research Protections, DHHS, acting on behalf of the Secretary, that the IRB approved the research and fulfilled its duties under 45 CFR 46.305(a)(2) – (7) and determined and documented that
   - (i) The research presents no more than minimal risk and no more than inconvenience to the prisoner-subjects, and
   - (ii) Prisoners are not a particular focus of the research.”

Additional Criteria for Approval
In order to approve research involving prisoners the IRB must determine that the following criteria (from 45 CFR 46.305) are met.

1. the research under review represents one of the categories of research permissible under §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 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 principal investigator provides to the Board justification in writing for following some 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 which 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 Board 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.”

Certification
For HHS conducted or supported research, MSU must certify and receive approval from the HHS Secretary before the research may be conducted at the institution. The institution must certify to the Secretary that the IRB has approved the research under 45 CFR 46.305 and the Secretary must determine that the proposed research involves solely the types of research described in 45 CFR 46.306 (unless the Secretarial waiver is applicable).

“The institution shall certify to the Secretary, in such form and manner as the Secretary may require, that the duties of the Board under this section have been fulfilled.” 45 CFR 46.305(c)

Documentation
Review and approval research involving prisoners follows the procedures as required by the level of review. See HRPP Manual 8-2 “Expedited Review Procedure” and/or 8-3 “Full Board Review Procedure” for policies and procedures on review and documentation required for research involving prisoners.

Additional Considerations
For research studies subject to the requirements of the U.S. Department of Justice, see HRPP Manual 2-2-C “U.S. Department of Justice.”