IRB Assessment of Risk & Benefit for Research Involving Prisoners (Subpart C)

45 CFR 46.303 (HHS – Subpart C): Definition of a Prisoner:

| Prisoner | 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. |
| Parolee | 1. If released to parole status but are still being detained (i.e. parolees who are detained in residential treatment (residing in a treatment center) as a condition of parole (which is an alternative to incarceration in a penal institution) are prisoners, for purposes of research taking place within that facility.  
2. If released to the community, not a prisoner. |
| Probationer | Not prisoners. |

**Minimal Risk:** For research involving prisoners, the definition of minimal risk differs from the definition of minimal risk that UCI IRB has adopted. As used in this policy, “minimal risk” is defined 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 examinations of healthy persons.

**45 CFR 46.305(a)(1-7):** The IRB must assure that all of the seven criteria have been met. Refer to Section 2 of the Reviewer’s Supplemental Checklist “C” for Prisoners.

**45 CFR 46.306(a)(2):** The IRB must decide which one of the categories listed below best represents the proposed research:

- §46.306(a)(2)(i): 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 participants.
- §46.306(a)(2)(ii): 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 participants.
- §46.306(a)(2)(iii): Research on conditions particularly affecting prisoners as a class (e.g., 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 addictions, and sexual assaults).
- §46.306(a)(2)(iv): Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the participant. (If federally supported, must be submitted to the Secretary of HHS (through OHRP) for approval."
- The study is epidemiologic research to describe the prevalence or incidence of a disease by identifying all cases or to study potential risk factor associations for a disease, where prisoners are not a particular focus of the research [FR Doc. 03-15580 6-19-03].

* California Penal Code 3502 prohibits biomedical research involving prisoners. Therefore, the UCI IRB will not approve prisoners to be involved in biomedical research studies. Biomedical research is defined by CA law as, “research relating to or involving biological, medical or physical science.”