

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 if so, if there are specific study activities which are in the best interests of the subject and should continue until the IRB is able to review the research study under Subpart C.

- iii. If the participant should continue, one of two options are available:
 - 1. Keep the participant enrolled in the study and review the research under Subpart C. If some of the requirements of Subpart C cannot be met or are not applicable (e.g., procedures for the selection of subjects within the prison), but it is in the best interests of the participant to remain in the study, keep the participant enrolled and inform OHRP of the decision along with the justification.
 - 2. Terminate enrollment of the participant from the study and keep the participant on the study intervention under an alternate mechanism such as compassionate use, off label use, etc.
- iv.

- vi. Adequate assurance exists that parole boards (or similar bodies constituted to make parole decisions) 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
- vii. Where the WCU 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.

VII. References

DHHS, OHRP. Code of Federal Regulations. Subpart C: Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects

[http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpar/in\(t5\(w\)50.50ar\)5 5\)-052.0IP01 \(na 01 e4\(#\)\)1d1bp](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpar/in(t5(w)50.50ar)5 5)-052.0IP01 (na 01 e4(#))1d1bp)