Appendix U

Waiver for Prisoner Subjects

Due to the population-based design of PRAMS at the state level, prisoner subjects may be included in the PRAMS sample. Prisoner subjects cannot be prospectively or retrospectively identified in a systematic manner from the sampling frame. Therefore, the PRAMS protocol is **required** to be reviewed under subpart C of the HHS regulations for protection of human research subjects governing inclusion of prisoners in research.

CDC PRAMS requested that the CDC IRB waive the applicability of certain provisions of subpart C of the HHS regulations for protection of human research subjects since the PRAMS project is an HHS conducted and supported epidemiologic research involving prisoners as subjects. This research meets the criteria described in an HHS Secretarial waiver that applies to certain epidemiological research (68 FR 36929, June 20, 2003). We specifically requested that a waiver be granted of 45 CFR 46.305(a)(1) and 46.306 (a)(2) for the PRAMS protocol.

The justification for the waiver is as follows:

> 1) PRAMS is an epidemiologic study conducted to describe the prevalence of health outcomes/behaviors by identifying all cases, or to study potential risk factor associations for a disease or behavior; and
>
> 2) PRAMS fulfilled its duties under 45 CFR 46.305(a) (2)–(7) since the CDC IRB previously approved the research and determined that it presents no more than minimal risk to subjects. Prisoners included in the study will be at no more inconvenience than other subjects. The PRAMS protocol includes prisoners as subjects only incidentally and does not specifically target prisoners for research.

PRAMS meets the criteria for waiver of the applicability of 45 CFR 45.305(a)(1) and 46.306(a)(2) and the CDC IRB approved to waive certain provisions of subpart C of 45 CFR 46. However, the waiver requires that when prisoners are used as subjects, each prisoner is clearly informed in advance that participation in the research will have no effect on parole. The informed consent documents were revised to include language regarding prisoner subjects. See **Appendix I (Mailed Informed Consent Document)** for more information.

The HHS Office of Human Research Protections (OHRP) in Washington, DC concurred with the CDC IRB's approval of the waiver and requires reviewing Institutional Review Boards to have a prisoner representative member who is present during the approval of inclusion of prisoners, and that IRB must certify to OHRP that the IRB fulfilled its duties. States with prisoner representatives on the local IRB must certify their review of the PRAMS protocol to OHRP by sending a letter to OHRP documenting that the protocol

was reviewed under subpart C. OHRP must concur with the determination and send a certification letter back to the local IRB. Local Institutional Review Boards without prisoner representatives can execute an IRB authorization agreement with CDC IRB to rely on its review under subpart C.

For additional information, please visit: http://www.hhs.gov/ohrp/special/prisoners/

If a state has a law, statute, or regulation that prohibits inclusion of incarcerated mothers in PRAMS, which means electing not to conduct active follow-up on any woman who is later identified as being a prisoner, the state should specifically document the justification for the decision not to include prisoners in **Chapter 10 (Human Subjects)** of the protocol.