

Appendix H. Office of Human Research Protections Certification

DEPARTMENT OF HEALTH & HUMAN SERVICES

**Public Health
Service
Office of Public Health and
Science**

**Office for Human Research Protections
Department of Health and Human Services
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January 18, 2007

Wendy Vissher, Ph.D.
Director, RTI Office of Research Protection
3040 Cornwallis Road
P.O. Box 12194
Research Triangle Park, NC 27709-2194

OHRP Assurance: FWA# 0003331, IRB# 00000654
DHHS/ASPE Grant: #HHS P23320062920YC
Title of Grant and Protocol: *Evaluation of the Marriage and Family
Strengthening Grants for Incarcerated and Reentering Fathers and their
Partners*
Principal Investigator: Anupa Bir

**Re: 1) OHRP receipt of 45 CFR 46.305 Prisoner Research Certification
2) OHRP concurrence with IRB determination of 45 CFR 46.305(a)(2)
(iv)**

Dear Dr. Vissher:

The Office for Human Research Protections (OHRP) acknowledges receipt January 14, 2008 of your institution's certification request that the research protocol listed above was reviewed by the IRB on December 12, 2007 and that the IRB fulfilled its duties under 45 CFR Part 46, Subpart C.

A duly authorized agent of your institution (e.g., the IRB Chairperson or other suitable official) certifies that the designated IRB for your institution reviewed and

approved this protocol only after finding and documenting that it satisfied the seven considerations enumerated in 45 CFR 46.305.

OHRP is authorized to determine whether proposed research that is either conducted or supported by the Department of Health and Human Services (DHHS) fits into any of the four enumerated categories in 45 CFR 46.306(a)(2). Based on the information received to date, OHRP concurs with the cited category, 45 CFR 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 subject.”

This is a multi-site evaluation of the implementation and impact of the 14 marriage and family strengthening initiatives funded by the Office of Family Assistance, Administration of Children and Families. Sites are implementing a variety of program components, typically delivered in a correctional facility, including marriage education, marriage or family counseling, parenting classes, employment or financial services, and case management. Incarcerated males and their partners will be interviewed at baseline, 9 and 18 months. This study is authorized to include prisoners as subjects.

OHRP appreciates your commitment to the protection of human research subjects. Please feel free to contact me should you have any questions.

Sincerely,

Julia Gorey, J.D.
Prisoner Research Coordinator
OHRP

cc: Ivor Pritchard., Ph.D.
Melody Lin, Ph.D., OHRP
Julie Kaneshiro, M.A., OHRP
Irene Stith-Coleman, Ph.D., OHRP
Linda Mellgren, Ph.D., ASPE