

John,

Below is the program's response to the Oklahoma Study Conference call that we had last week. Please let me know if you have any additional questions, comments, or concerns.

Seleda

Seleda M. Perryman

HHS Reports Clearance Officer

Office of Resources Management

Office of the Chief Information Officer

Office of the Assistant Secretary for Resources and Technology

U.S. Department of Health and Human Services

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1.) This data collection was approved by the HHS Office for Human Research Protections (OHRP) on April 18, 2007. The approval letter is attached.

2.) We followed up on OMB's question about the efficacy of incentive payments of \$35 for prisoner participation in focus groups. Based on the experience of other studies that have conducted research with prisoners, it appears that providing such incentives is the usual practice for these kinds of evaluations. Given this, and OHRP approval of the study protocols, we would like to be able to provide these incentive payments to prisoners or their families as originally proposed. (The focus groups for this study will ask participants to discuss how participation in marriage skills education classes has affected their relationship or marriage, among other things. The incentive payment could go to the prisoner's family rather than directly to the prisoner.)

3.) Based on further analysis, we have revised our response to Section A.10, Confidentiality of the Data. The revised response is below. For further information we have also attached the participant consent forms with have been approved by MPR's institutional review board through Public Private Ventures and by the HHS Office for Human Research Protections.

10. CONFIDENTIALITY OF THE DATA

The records associated with this study will be collected, maintained, secured, and disposed of in accordance with the Privacy Act of 1974, as amended. ASPE has an established system of records notice for studies conducted by its contractors that covers the records produced in this study. Each respondent will be asked to sign a consent form that describes confidentiality protections at the beginning of the interview or focus group. Additionally, at the beginning of each focus group or interview all respondents will be told that (1) their participation in the interview or focus group is voluntary; (2) the information they provide will be combined with other participants' answers and used only for the study; and (3) their names will never be used in reporting the results. Although the records produced in the study are not covered by the Confidential Information and Statistical Efficiency Act (CIPSEA), so that participants are not promised complete confidentiality for their records, the consent form describes the procedures that will be followed in plain language and the fact that "in rare cases, information may be released, if required by law."

No identifying information will be attached to any reports or data supplied to the U.S. Department of Health and Human Services. MPR routinely employs the following safeguards:

-Project staff responsible for the data collection will be fully informed of MPR's policies and procedures regarding confidentiality of interview and records data. They will be trained to remind interview respondents of these procedures when they are administering these protocols.

-All employees at MPR sign a confidentiality pledge that emphasizes the importance of confidentiality and describes their obligations. MPR views releasing information that is confidential or that is proprietary to the company as a breach of trust and as such, employees may be subject to corrective action, up to, and including, termination of employment.

-To the extent that locating is necessary for recruiting, identifying information is maintained on separate forms (called contact sheets), which are linked to respondents by a sample identification number. Access to the file linking sample identification numbers with the respondents' identification and contact information is limited to a small number of individuals who have a need to know this information.

-Access to sample selection data with personal identifying information is limited to those directly responsible for providing the sample. At the conclusion of the research, these data are destroyed.

-Access to computer files and hard-copy documents (such as contact sheets and locating packets) is strictly limited. Physical precautions include the use of PC's with password protection, secure areas, locked files and cabinets, and shredding of discarded materials.

These data collection procedures have been approved by an Institutional Review Board through Public/Private Ventures in Philadelphia, PA, and by the U.S. Department of Health and Human Services Office for Human Research Protections.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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April 18, 2007

Robin Dion, M.D., Senior Researcher
Mathmatica Policy Research, Inc.
600 Maryland Avenue, SW, Suite 550
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Subject: DHHS/ASPE Contract: 233-02-00086 TK 26 HHSP233000026T
Task Order Title: *Oklahoma Marriage Initiative Process Evaluation*
Principal Investigator: Robin Dion, M.D.
Contractor: Mathmatica Policy Research, Inc., FWA# 00000340
IRB of Record: Public/Private Ventures, IRB# 00000830

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

Dear Dr. Dion:

The Office for Human Research Protections (OHRP) acknowledges receipt April 6, 2007 of your institution's certification dated April 3, 2007, that the research protocol listed above was reviewed by the IRB on January 26, 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.

The IRB at your institution has cited Section 45 CFR 46.306(a)(2)(i) as the proposed category under which prisoners may be involved as human subjects in this protocol. This category requires 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 subjects. @

Based on the information received to date, OHRP concurs that this study is appropriately categorized under 45 CFR 46.306(a)(2)(i). The purpose of this ASPE funded contract is to evaluate the Oklahoma Marriage Initiative (OMI), an initiative designed to reduce divorce and nonmarital childbearing through the delivery of marriage and relationship skills education. The evaluation includes a special emphasis on the Prison PREP component within OMI, which seeks strategies to help parents keep their marital and parent-child relationships intact during incarceration and as they attempt to re-enter society. The evaluation will include focus groups, semi-structured interviews with lead program staff at public agencies, and group interviews with workshop instructors. This study is authorized to include incarcerated 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: Bernard Schwetz, D.V.M., Ph.D.
Melody Lin, Ph.D., OHRP
Julie Kaneshiro, M.A., OHRP
Irene Stith-Coleman, Ph.D., OHRP
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