

DEPARTMENT OF HEALTH & HUMAN SERVICES

SERVICES Public Health Service
Office of the Assistant Secretary of Health

Office for Human Research Protections
Department of Health and Human Services
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11/29/2016

Kimberly Kendziora, Ph.D. Chair, AIR, IRB American Institutes For Research 1000 Thomas Jefferson Street NW Washington, DC 20007-3835

OHRP Assurance: FWA# 00003952, IRB# 00000436

DHHS Grant: GS10F0112J

Title of Grant and Study: Development of Standardized Measure To Assess

Disparate Contextual Forms of Intimate Partner Violence (IPV)

Principal Investigator: Melissa Scardaville, Ph.D.

Re: 1) OHRP receipt of 45 CFR 46.305(c) 46.306(a)(2)(iii) Prisoner Research

Certification

2) OHRP non-concurrence with category 45 CFR 46.306(a)(2)(iii)

3) OHRP determination of category 45 CFR 46.306(a)(2)(i)

Dear Dr. Kendziora,

The Office for Human Research Protections (OHRP) acknowledges receipt 11/28/2016 of your institution's 11/8/2016 certification request that the research protocol listed above was reviewed by the IRB on 11/4/2016 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 does not concur with the cited category 45 CFR 46.306(a)(2)(iii) and has determined that

this research can be more appropriately placed within category 45 CFR 46.306(a)(2)(i), "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."

This CDC-funded survey study examines associations between social, environmental, and behavioral factors and patterns of Intimate Partner Violence (IPV) perpetration, with the goal of identifying factors that influence IPV perpetration. Data will be used for the long-term development of tailored perpetration intervention programs. Collecting data on incarcerated offenders allows the analysis of data from individuals whose predictors of IPV may be more prevalent, and whose experiences and characteristics may be different from those of the non-incarcerated population. This data may be valuable in identifying indicators that predict patterns of perpetration. This study is authorized to include prisoners in human subjects research.

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: Wendy McIntosh, Ph.D., CDC