

Appendix R: Certificate of Review from the Institutional Review Board (IRB) of the University of North Carolina-Chapel Hill



THE UNIVERSITY
of NORTH CAROLINA
at CHAPEL HILL

OFFICE OF HUMAN RESEARCH ETHICS
Medical School Building 52
Mason Farm Road
CB #7097
Chapel Hill, NC 27599-7097
(919) 966-3113
Web site: ohre.unc.edu
Federalwide Assurance (FWA) #4801

To: Iheoma Iruka
Frank Porter Graham Child Dev Center

From: Non-Biomedical IRB

Approval Date: 7/02/2013

Expiration Date of Approval: 7/01/2014

RE: Notice of IRB Approval by Expedited Review (under 45 CFR 46.110)

Submission Type: Initial

Expedited Category: 7.Surveys/interviews/focus groups

Study #: 13-2124

Study Title: Head Start Designation Renewal System Evaluation Project

This submission has been approved by the IRB for the period indicated. It has been determined that the risk involved in this research is no more than minimal.

Study Description:

Purpose: The purpose of the evaluation is to understand if the Head Start Designation Renewal System is working as intended, as a valid, reliable, and transparent method for identifying high-quality programs that can receive continuing five-year grants without competition and as a system that encourages overall quality improvement over time.

Participants: Up to 70 Head Start programs and 830 classrooms with 1 teacher per classroom and the associated center director and program grantee-level director.

Procedures (methods): The study will use classroom observations and teacher interviews, health and safety checklists, and interviews with program directors to collect data on program quality in the spring of 2014.

This is a joint project between the Urban Institute (lead agency) and the research team at the Frank Porter Graham Child Development Institute (subcontractor). Each organization will undertake a separate part of the study. The Urban Institute will conduct the qualitative portion utilizing interviews with Head Start directors at various levels. That part of the study will be under the purview of the Urban Institute IRB. FPG will be responsible for participant recruitment and consent and the quantitative portion of the study including interviews and surveys of center directors and

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teachers and classroom observation. The UNC IRB will be responsible for overseeing this section and UNC personnel. Only this part of the study will be described in this protocol.

Regulatory and other findings:

The IRB has determined that the study-specific rationale provided by the investigator is sufficient to justify a waiver of written (signed) consent according to 45 CFR 46.117(c)(2). Program and center directors will provide verbal consent for their sites to participate.

Investigator's Responsibilities:

Federal regulations require that all research be reviewed at least annually. It is the Principal Investigator's responsibility to submit for renewal and obtain approval before the expiration date. You may not continue any research activity beyond the expiration date without IRB approval. Failure to receive approval for continuation before the expiration date will result in automatic termination of the approval for this study on the expiration date.

Your approved consent forms and other documents are available online at http://apps.research.unc.edu/irb/irb_event.cfm?actn=info&irbid=13-2124.

You are required to obtain IRB approval for any changes to any aspect of this study before they can be implemented. Any unanticipated problem involving risks to subjects or others (including adverse events reportable under UNC-Chapel Hill policy) should be reported to the IRB using the web portal at <http://irbis.unc.edu>.

Researchers are reminded that additional approvals may be needed from relevant "gatekeepers" to access subjects (e.g., principals, facility directors, healthcare system).

This study was reviewed in accordance with federal regulations governing human subjects research, including those found at 45 CFR 46 (Common Rule), 45 CFR 164 (HIPAA), 21 CFR 50 & 56 (FDA), and 40 CFR 26 (EPA), where applicable.

CC:

Margaret Burchinal, Frank Porter Graham Child Dev Center
Allison De Marco, Frank Porter Graham Child Dev Center

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To: Iheoma Iruka
Frank Porter Graham Child Dev Center

From: Non-Biomedical IRB

Approval Date: 7/03/2013

Expiration Date of Approval: 7/01/2014

RE: Notice of IRB Approval by Expedited Review (under 45 CFR 46.110)

Submission Type: Modification

Expedited Category: Minor Change to Previously Approved Research

Study #: 13-2124

Study Title: Head Start Designation Renewal System Evaluation Project

This submission has been approved by the IRB for the period indicated. It has been determined that the risk involved in this modification is no more than minimal. Unless otherwise noted, regulatory and other findings made previously for this study continue to be applicable.

Submission Description:

I am correcting numbers in the General Information/brief summary that I overlooked with the resubmission. It should now be 560 classrooms instead of 830.

Investigator's Responsibilities:

Your approved consent forms and other documents are available online at http://apps.research.unc.edu/irb/irb_event.cfm?actn=info&irbid=13-2124.

This study was reviewed in accordance with federal regulations governing human subjects research, including those found at 45 CFR 46 (Common Rule), 45 CFR 164 (HIPAA), 21 CFR 50 & 56 (FDA), and 40 CFR 26 (EPA), where applicable.

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