

**Appendix A – University of North Carolina Institutional Review Board
Approval Memo for Formative Research**

A paper copy of the approval memo and any relevant documents are being mailed today.

To: Barbara Entwisle
Carolina Population Center
CB# 8120

From: Public Health-Nursing IRB

Authorized signature on behalf of IRB

Approval Date: 11/18/2008
Expiration Date of Approval: 12/10/2008

RE: Notice of IRB Approval by Expedited Review (under 45 CFR 46.110)
Submission Type: Modification
Expedited Category: Minor Change to Previously Reviewed Research
Study #: 05-1321 (Former IRB Number 05-2848)

Study Title: National Children's Study, Vanguard Center in Duplin County (NCS-VC-Duplin)

This submission has been approved by the above 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:

This amendment, dated 10/16/2008, adds ten focus groups to the study that will be conducted in Duplin County, NC. The purpose of these focus groups is to investigate whether conducting small group informational meetings about the NCS as a community engagement strategy will encourage the participation of Latina/o and undocumented workers in the study.

Other Regulatory Findings:

This research meets criteria for a waiver of written (signed) consent according to 45 CFR 46.117(c)(2) for the focus groups.

Study Specific Details:

Please submit final versions of the English and Spanish recruitment scripts, fact sheets,

and moderator guides prior to using them with participants.

Investigator's Responsibilities:

When applicable, enclosed are stamped copies of approved consent documents and other recruitment materials. You must copy the stamped consent forms for use with subjects unless you have approval to do otherwise.

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:

Deborah Bailey, Carolina Population Center

Jill Fuller, Carolina Population Center

IRB Informational Message—please do not use email REPLY to this address