



IRB ID Number: 13483

**Office of Research Protection  
Institutional Review Board Notice of Approval**  
Federalwide Assurance No. 3331

**Title of Study:** Evaluation of CDC's National Tobacco Education Campaign  
**RTI Project Number:** 0210637.029.000 **RTI Proposal Number** (if no Project Number)  
**Project Leader:** Kevin Davis  
**Project Team Member Contact** (if different from Project Leader):  
**Source of Funding for this Study:** CDC  
**Date Submitted to IRB:** 04-28-2015

**Level of Review** (check one):

Full , IRB Meeting Date:

Expedited , category: **M: Minor changes in approved research**

**Type of Review** (check one):

Preliminary review (For DHHS grants where RTI is prime, the grant application/contract proposal and protocol submitted to the IRB are in concordance (45 CFR 46.103(f)). **Do not involve human subjects or data until pretest or full study is approved.**)

Amendment, describe: sample size increase and revised survey instruments for Waves 6 and 7

Add study site(s): \_\_\_\_\_

Pretest/Pilot Test \_\_\_\_\_

Full Implementation \_\_\_\_\_

Renewal

Study Closure

**IRB Approval of Special Conditions** (check all that apply to this review):

Waiver of Signed Informed Consent/Parental Permission

Waiver of elements of Informed Consent or requirement for Informed Consent/Parental Permission

Participation of Pregnant Women (**Worksheet B** submitted by project team)

Participation of Prisoners (**Worksheet C** submitted by project team)

Participation of Prisoners in DHHS-funded studies (OHRP acknowledgement required)

Participation of Minors (**Worksheet D** submitted by project team)

IRB Agreement of Nonsignificant Risk Device Study Determination

HIPAA Waiver of Authorization

**Please note the following requirements:**

- If **unexpected problems** or **adverse events** occur, the project team must notify the IRB.
- If there are **changes** in study procedures or protocol or any data collection materials (brochures, letters, questionnaires, etc.) the project team must notify the IRB before they are implemented.
- The project team is required to apply for **continuing review** as long as the study is active, which includes participation of human subjects or possession of human data or specimens.

**Expiration Date of IRB Approval:** 01-14-2016

(No human subjects research can occur after this date without continuing review and approval.)

**04-29-2015**

\_\_\_\_\_  
**Signature - IRB Member or Chair**

\_\_\_\_\_  
**Date of IRB Approval**

\_\_\_\_\_  
Jamia Bachrach, JD

\_\_\_\_\_  
**Name - IRB Member or Chair (print or type)**

Copy sent to project leader on: \_\_\_\_\_

Entered into MIS

OHRP acknowledgement received for participation of prisoners in DHHS-funded studies on: \_\_\_\_\_



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Full , IRB Meeting Date:

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Amendment, describe: sample size increase for Waves 8-10

Add study site(s): \_\_\_\_\_

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Full Implementation \_\_\_\_\_

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05-14-15

\_\_\_\_\_  
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Date of IRB Approval

Jamia Bachrach, JD

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