RTI INTERNATIONAL

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.)

Jan I Bachrach

Signature - IRB Member or Chair

04-29-2015
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:_____

Office of Research Protection and Ethics, Institutional Review Board
3040 Cornwallis Road, Research Triangle Park, NC 27709-2194, USA
Telephone: 919-316-3358 Fax: 919-316-3897 orpe@rti.org

RTI INTERNATIONAL

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: 05-12-2015
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 for Waves 8-10
☐ 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.)

Jam I Bachrach

Signature - IRB Member or Chair

05-14-15
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:_____

Office of Research Protection and Ethics, Institutional Review Board
3040 Cornwallis Road, Research Triangle Park, NC 27709-2194, USA
Telephone: 919-316-3358 Fax: 919-316-3897 orpe@rti.org