IRB ID Number: 13237

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

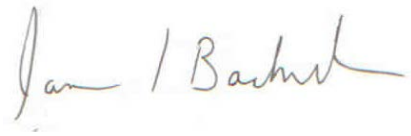
**Title of Study:** Perceptions of Health Risk from Smokeless Tobacco Products and Nicotine Replacement Therapy among Pregnant Women and Women Planning a Pregnancy
**RTI Project Number:** 0211965.032.000 **RTI Proposal Number** (if no Project Number)
**Project Leader:** Julia Kish Doto
**Project Team Member Contact** (if different from Project Leader): Katherine Kosa
**Source of Funding for this Study:** CDC
**Date Submitted to IRB:** May 21, 2013
**Level of Review** *(check one)*:
**Full** ☐, IRB Meeting Date:
**Expedited** ☒**,** category: M: Minor changes in approved research

**Type of Review** *(check one)*:
☐Preliminary review (The grant application/contract proposal and protocol submitted to the IRB are in concordance with regard to the scientific conduct of the study, informed consent content, and all other issues pertaining to the protection of human subjects. (45 CFR 46.103(f)) **Do not involve human subjects or data until pretest or full study is approved.**)
☒Amendment, describe: revised moderator's guide
☐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: November 19, 2013**
(No human subjects research can occur after this date without continuing review and approval.)



**Signature - IRB Member or Chair**

**May 23, 2013**
**Date of IRB Approval**

Jamia Bachrach
**Name - IRB Member or Chair (print or type)**

☒Copy sent to project leader on: May 23, 2013
☐Entered into MIS
☐ OHRP acknowledgement received for participation of prisoners in DHHS-funded studies on:_____

Office of Research Protection, Institutional Review Board
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