

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

**Title of Study:** Qualitative Study on Nicotine Exposure Risk: Knowledge, Beliefs, Perceptions, and Behaviors

**RTI Project Number:** 0214634.010

**RTI Proposal Number** (if no Project Number):

**Project Leader:** Jennifer Alexander

**Project Team Member Contact** (if different from Project Leader):

**Source of Funding for this Study:** FDA

**Date Submitted to IRB:** January 3, 2018

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

Full , IRB Meeting Date:

Expedited , category: **7: Behavioral - surveys, focus groups, etc.**

**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:

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:** 01-04-2019

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



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

**01-04-2018**

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

Ina Wallace, Ph D

\_\_\_\_\_  
**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: \_\_\_\_\_