

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

Title of Study: Point of Sale Intervention for Tobacco Evaluation (POSITeV)
RTI Project Number: 0213772.003.001.005 RTI Proposal Number (if no Project Number):
Project Leader: Matthew Farrelly
Project Team Member Contact (if different from Project Leader): Lauren Dutra
Source of Funding for this Study: FDA
Date Submitted to IRB: October 26, 2017
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: October 26, 2018

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



October 26, 2017

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: October 26, 2017
- Entered into MIS
- OHRP acknowledgement received for participation of prisoners in DHHS-funded studies on: _____