IRB ID Number: 13984

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

Title of Study: Consumer Comprehension of Displays of Harmful and Potentially Harmful Constituents (HPHC 2) in Tobacco Products
RTI Project Number: 0212926.033.000.001 **RTI Proposal Number** (if no Project Number):
Project Leader: Jon Blitstein
Project Team Member Contact (if different from Project Leader): Jennifer Alexander
Source of Funding for this Study: FDA
Date Submitted to IRB: August 23, 2016
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: June 9, 2017
(No human subjects research can occur after this date without continuing review and approval.)

Ina Wallace

Signature - IRB Member or Chair

08-29-2016
Date of IRB Approval

Ina Wallace, PhD
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, Institutional Review Board
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