

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.)



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: _____