

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

Title of Study: Formative Focus Groups on Cigarette Smoking During Pregnancy and Adverse Outcomes, Including Birth Defects

RTI Project Number: 0210637.009.001.005 **RTI Proposal Number** (if no Project Number)

Project Leader: Brenda Stone-Wiggins

Project Team Member Contact (if different from Project Leader): Mary Council

Source of Funding for this Study: CDC

Date Submitted to IRB: September 15, 2009

Level of Review (*check one*):

Full , IRB Meeting Date:

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

Type of Review (*check one*):

Preliminary review (Do not involve human subjects or data until pretest or full study is approved.)

Pretest/Pilot Test

Full Implementation:

Amendment, describe:

Add study site(s):

Renewal

Study Closure

IRB Approval of Special Conditions (*check all that apply*):

Waiver of Signed 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 received)

Participation of Minors (**Worksheet D** submitted by project team)

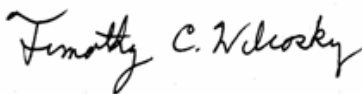
IRB Agreement of Nonsignificant Risk Device Study Determination

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: September 16, 2010

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



Signature - IRB Member or Chair

September 16, 2009

Date of IRB Approval

Timothy C. Wilcosky, Ph.D.

Name - IRB Member or Chair (print or type)

Copy sent to project leader on: September 17, 2009

Entered into MIS