

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

Title of Study: Formative Focus Groups on Women, Alcohol and Reproductive Health
RTI Project Number: 0210637.009.001.003 **RTI Proposal Number** (if no Project Number)
Project Leader: Elvira Elek
Project Team Member Contact (if different from Project Leader):
Source of Funding for this Study: CDC
Date Submitted to IRB: July 10, 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: July 17, 2010
 (No human subjects research can occur after this date without continuing review and approval.)

Ina Wallace

July 17, 2009

Signature - IRB Member or Chair

Date of IRB Approval

Ina Wallace, PhD

Name - IRB Member or Chair (print or type)

Copy sent to project leader on: July 17, 2009
 Entered into MIS