IRB ID Number: 12234

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

Title of Study: Formative Research to Support the Division of Birth Defects and Development Disabilities Project 1: Formative Research on Preconception Health Issues (Phase 1)
RTI Project Number: 0210637.009.001.001 **RTI Proposal Number** (if no Project Number)
Project Leader: Linda Squiers
Project Team Member Contact (if different from Project Leader): Molly Lynch
Source of Funding for this Study: CDC
Date Submitted to IRB: January 7, 2010
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 (for telephone interviews)
☐ 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

Signature - IRB Member or Chair

January 8, 2010
Date of IRB Approval

Ina Wallace, PhD
Name - IRB Member or Chair (print or type)

☒ Copy sent to project leader on: January 8, 2010
☐ Entered into MIS

Office of Research Protection, Institutional Review Board
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