

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.)



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