

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

**Title of Study:** Formative Research with Couples about Reproductive Life Planning and Preconception Health Issues

**RTI Project Number:** 0210637.001.002 **RTI Proposal Number** (if no Project Number)

**Project Leader:** Megan Lewis

**Project Team Member Contact** (if different from Project Leader): Karen Isenberg

**Source of Funding for this Study:** CDC

**Date Submitted to IRB:** November 30, 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:** December 2, 2010

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



\_\_\_\_\_  
**Signature - IRB Member or Chair**

**December 2, 2009**

\_\_\_\_\_  
**Date of IRB Approval**

Ina Wallace, PhD

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**Name - IRB Member or Chair (print or type)**

Copy sent to project leader on: December 2, 2009

Entered into MIS