IRB ID Number: 12464

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

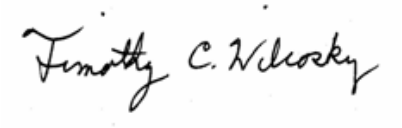
Title of Study: Formative Research to Understand Women's Perceptions about Down Syndrome
RTI Project Number: 0210637.009.001.004 **RTI Proposal Number** (if no Project Number)
Project Leader: Nedra Whitehead
Project Team Member Contact (if different from Project Leader): Lisa Kilpatrick
Source of Funding for this Study: CDC
Date Submitted to IRB: September 14, 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

Office of Research Protection, Institutional Review Board
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