

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

**Title of Study:** Bureau of Primary Health Care Patient Surveys  
**RTI Project Number:** 0210201.002/0210201.003 **RTI Proposal Number** (if no Project Number)  
**Project Leader:** Kristine Fahrney  
**Project Team Member Contact** (if different from Project Leader):  
**Source of Funding for this Study:** BPHC  
**Date Submitted to IRB:** February 5, 2009  
**Level of Review** (*check one*):  
**Full** , IRB Meeting Date:  
**Expedited** , category: M: Minor changes in approved research

**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: main study questionnaire; revised consent/assent forms; revised screener update; revised grantee recruitment guidelines; revised letter of agreement; revised data security plan
- 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:** March 18, 2009

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

*Wendy Visscher*

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

**02-06-2009**

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

Wendy Visscher, PhD

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

- Copy sent to project leader on:
- Entered into MIS