IRB ID Number: 11947

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

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