

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: March 18, 2009

Level of Review (check one):

Full , IRB Meeting Date:

Expedited , category: 9: Cont. Rev. minimal risk 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:

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, 2010

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



Signature - IRB Member or Chair

3-18-09

Date of IRB Approval

Wendy Visscher, PhD

Name - IRB Member or Chair (print or type)

Copy sent to project leader

Entered into MIS