

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

Title of Study: Insurance Coverage, Employment Status, and Copayments/Deductibles Faced by Young Women Diagnosed with Breast Cancer

RTI Project Number: 0211965.048

RTI Proposal Number (if no Project Number)

Project Leader: Sujha Subramanian

Project Team Member Contact (if different from Project Leader):

Source of Funding for this Study: CDC

Date Submitted to IRB: August 27, 2015

Level of Review (check one):

Full , IRB Meeting Date:

Expedited , category: **7: Behavioral - surveys, focus groups, etc.**

Type of Review (check one):

Preliminary review (For DHHS grants where RTI is prime, the grant application/contract proposal and protocol submitted to the IRB are in concordance (45 CFR 46.103(f)). **Do not involve human subjects or data until pretest or full study is approved.**)

Amendment, describe:

Add study site(s): _____

Pretest/Pilot Test:

Full Implementation _____

Renewal

Study Closure

IRB Approval of Special Conditions (check all that apply to this review):

Waiver of Signed Informed Consent/Parental Permission

Waiver of elements of Informed Consent or requirement for 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 required)

Participation of Minors (**Worksheet D** submitted by project team)

IRB Agreement of Nonsignificant Risk Device Study Determination

HIPAA Waiver of Authorization

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: February 19, 2016

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



Signature - IRB Member or Chair

August 27, 2015

Date of IRB Approval

Ina Wallace, PhD

Name - IRB Member or Chair (print or type)

Copy sent to project leader on: August 27, 2015

Entered into MIS

OHRP acknowledgement received for participation of prisoners in DHHS-funded studies on: _____