

Attachment A-6: RTI Institutional Review Board Approval



IRB ID Number: 13336

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

Title of Study: Using Conjoint Analysis to Understand Individual Decisions about Health-Risk Behaviors and Cancer Screening

RTI Project Number: 0211965.025.001 RTI Proposal Number (if no Project Number)

Project Leader: Carol Mansfield

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

Source of Funding for this Study: CDC

Date Submitted to IRB: July 22, 2013

Level of Review (check one):

Full [], IRB Meeting Date: _____

Expedited [x], category: 7: Behavioral - surveys, focus groups, etc.

Type of Review (check one):

[] Preliminary review (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 _____

[x] Full Implementation _____

[] Renewal

[] Study Closure

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

[x] 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: May 8, 2014

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

Ina Wallace

July 26, 2013

Signature - IRB Member or Chair

Date of IRB Approval

Ina Wallace, PhD

Name - IRB Member or Chair (print or type)

[x] Copy sent to project leader on: 8-9-13

[] Entered into MIS

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



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RTI Project Number: 0211965.025.001 RTI Proposal Number (if no Project Number)

Project Leader: Carol Mansfield

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

Source of Funding for this Study: CDC

Date Submitted to IRB: November 13, 2013

Level of Review (check one):

Full [], IRB Meeting Date: _____

Expedited [x], category: M: Minor changes in approved research

Type of Review (check one):

[] Preliminary review (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.)

[x] Amendment, describe: revisions to survey questions

[] Add study site(s): _____

[] Pretest/Pilot Test _____

[] Full Implementation _____

[] Renewal

[] Study Closure

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

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Ina Wallace

November 13, 2013

Signature - IRB Member or Chair

Date of IRB Approval

Ina Wallace, PhD

Name - IRB Member or Chair (print or type)

[x] Copy sent to project leader on: 11-14-13

[] Entered into MIS

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