Attachment 6: RTI Institutional Review Board (IRB) Approval Letter

These are the IRB approval letters for the pilot study, pilot study telephone debriefing (via modification), and to begin the full survey. A renewal or modification (if required by as a result of the OMB clearance process) will be obtained as needed to complete the full survey.

RTI INTERNATIONAL

IRB ID Number: 12049

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

Title of Study: Research Integrity Officer Study
RTI Project Number: 0208490.034 **RTI Proposal Number** (if no Project Number)
Project Leader: Arthur Bonito
Project Team Member Contact (if different from Project Leader): _____
Source of Funding for this Study: Office of Research Integrity
Date Submitted to IRB: April 14, 2008

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: cognitive interview/survey questionnaire debriefing protocol
☐ 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: **February 12, 2009**
(No human subjects research can occur after this date without continuing review and approval.)

Ina Wallace

Signature - IRB Member or Chair

April 14, 2008
Date of IRB Approval

Ina Wallace, PhD
Name - IRB Member or Chair (print or type)

☒ Copy sent to project leader on: April 15, 2008
☐ Entered into MIS

Office of Research Protection, Institutional Review Board
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