

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

Title of Study: Parents Speak Up National Campaign (PSUNC) Evaluation
RTI Project Number 0208490.025 **RTI Proposal Number** (if no Project Number)
Project Leader: Doug Evans
Project Team Member Contact (if different from Project Leader): Christina Lynch
Source of Funding for this Study: Office of Population Affairs, DHHS
Date Submitted to IRB: December 18, 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: revised survey instrument, parental permission form, and teen assent form
 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: June 5, 2009

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



12-19-2008

Signature - IRB Member or Chair

Date of IRB Approval

Ina Wallace, Ph.D.

Name - IRB Member or Chair (print or type)

- Copy sent to project leader
 Entered into MIS