

Office of Research Protection Institutional Review Board Notice of Approval

Federalwide Assurance No. 3331

Title of Study: <u>National Inmate Survey</u> RTI Project Number: 0209778	RTI Proposal Number (if no Project Number)			
Project Leader: Rachel Caspar				
Project Team Member Contact (if different from Project Leader):				
Source of Funding for this Study: DOJ				
Date Submitted to IRB: September 24, 2009				
Level of Review (check one):				
Full ⊠, IRB Meeting Date: September 14, 2	<u>1009</u>			
Expedited , category: None				
Type of Review (check one):				

Preliminary review (Do not involve human subjects or data until pretest or full study is approved.)

Full Implementation

Amendment, describe: inclusion of 16 and 17-year old minors in the study, waiver of parental permission and a pilot test of the proposed changes at five facilities

Add study site(s):

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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 30, 2010

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

Wend lisscher

Signature - IRB Member or Chair

September 25, 2009 Date of IRB Approval

Wendy A. Visscher, PhD Name - IRB Member or Chair (print or type)

Copy sent to project leader on: <u>September 25, 2009</u> Entered into MIS