

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

Title of Study: Health-Related Quality of Life Study

RTI Project Number: 0211796.000.001 RTI Proposal Number (if no Project Number)

Project Leader: Derek Brown

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

Source of Funding for this Study: Centers for Disease Control and Prevention

Date Submitted to IRB: February 9, 2012

Level of Review (check one):

Full , IRB Meeting Date:

Expedited , category: 9: Cont. Rev. minimal risk research

Type of Review (check one):

Preliminary review (The grant application/contract proposal and protocol submitted to the IRB are in concordance with regard to the scientific conduct of the study, informed consent content, and all other issues pertaining to the protection of human subjects. (45 CFR 46.103(f)) **Do not involve human subjects or data until pretest or full study is approved.**)

Pretest/Pilot Test _____

Full Implementation _____

Amendment, describe: _____

Add study site(s): _____

Renewal

Study Closure

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

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 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: March 17, 2013

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



Signature - IRB Member or Chair

2/21/2012

Date of IRB Approval

Juesta Caddell, PhD

Name - IRB Member or Chair (print or type)

Copy sent to project leader

Entered into MIS

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